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[Discussion Draft]

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1	anticipated schedule for accommodating that
2	demand;
3	"(C) the capacity of the Environmental
4	Protection Agency to promulgate rules under
5	section 6(a) as required based on risk evalua-
6	tions conducted and published under section
7	6(b); and
8	"(D) the actual and anticipated efforts of
9	the Environmental Protection Agency to in-
10	crease the Agency's capacity to conduct and
11	publish risk evaluations under section 6(b).
12	"(2) Subsequent reports.—The Adminis-
13	trator shall update and resubmit the report de-
14	scribed in paragraph (1) not less frequently than
15	once every 5 years.
16	"(n) Annual Plan.—At the beginning of each cal-
17	endar year, the Administrator shall publish an annual plan
18	that—
19	"(1) identifies the chemical substances for
20	which risk evaluations are expected to be completed
21	that year and the resources necessary for their com-
22	pletion;
23	"(2) describes the status of each risk evaluation

that has been initiated but not yet completed; and

Commented [A45]: "the completion of the risk evaluations." - SLC

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[Discussion Draft]

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1	"(3) if the schedule for completion of a risk	
2	evaluation has changed, includes an updated sched-	
3	ule for that risk evaluation.	
4	"(0) Consultation With Science Advisory Com-	
5	MITTEE ON CHEMICALS.—	
6	"(1) ESTABLISHMENT.—Not later than 1 year	
7	after the date of enactment of the Frank R. Lauten-	
8	berg Chemical Safety for the 21st Century Act, the	
9	Administrator shall establish an advisory committee,	
10	to be known as the Science Advisory Committee on	
11	Chemicals (referred to in this subsection as the	
12	'Committee').	
13	"(2) Purpose.—The purpose of the Committee	
14	shall be to provide independent advice and expert	
15	consultation, at the request of the Administrator,	Commented [A46]: "on" in SLC version
16	with respect to the scientific and technical aspects of	
17	issues relating to the implementation of this title.	
18	"(3) Composition.—The Committee shall be	
19	composed of representatives of such science, govern-	
20	ment, labor, public health, public interest, animal	
21	protection, industry, and other groups as the Admin-	
22	istrator determines to be advisable, including rep-	Commented [A47]: "at a minimum" –
23	resentatives that have specific scientific expertise in	SLC version

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(626935|17)

the relationship of chemical exposures to women,

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[Discussion Draft]

1 children, and other potentially exposed or susceptible 2 subpopulations. "(4) SCHEDULE.—The Administrator shall con-3 vene the Committee in accordance with such sched-4 5 ule as the Administrator determines to be appropriate, but not less frequently than once every 2 6 7 years. "(p) Prior Actions.— 8 Commented [A48]: SLC treats (p)(1) as a separate subsection; treats (p)(2) and "(1) Rules, orders, and exemptions.— 9 (p)(3) as (q)(1) and (q)(2). Nothing in the Frank R. Lautenberg Chemical Safe-10 ty for the 21st Century Act eliminates, modifies, or 11 Commented [A49]: "this Act" - SLC version withdraws any rule promulgated, order issued, or ex-12 emption established pursuant to this Act before the 13 date of enactment of the Frank R. Lautenberg 14 Chemical Safety for the 21st Century Act. 15 16 "(2) Prior-initiated evaluations.—Nothing in the Frank R. Lautenberg Chemical Safety for the 17 18 21st Century Act prevents the Administrator from Commented [A50]: "this Act" - SLC version initiating a risk evaluation regarding a chemical sub-19 stance, or from continuing or completing such risk 20 21 evaluation, prior to the effective date of the policies, procedures, and guidance required to be developed 22 Commented [A51]: "established" - SLC version by the Administrator under this section or section 6. 23

"(3) ACTIONS COMPLETED PRIOR TO COMPLE-

TION OF POLICIES, PROCEDURES, AND GUIDANCE.-

N

f:\VHLC\041816\041816.296.xml April 18, 2016 (3:51 p.m.)

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(626935|17)

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section (1).".

[Discussion Draft]

18

Nothing in the Frank R. Lautenberg Chemical Safety for the 21st Century Act requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule under this Act solely because the action was completed prior to the development of a policy, procedure, or guidance under sub-

Commented [A52]: "this Act, or the amendments made by this Act" – SLC version

Commented [A53]: Not in SLC version

HLC clarification seems correct.

Commented [A54]: "completion" in SLC version

Commented [A55]: "new" in SLC version

Commented [A56]: SLC says "under this section or section 6"

This is a significant discrepancy. Just referring to subsection (I) would be sending a very definite signal that Congress intended other policies and procedures (i.e,. those established under 6) to give rise to obligations to revise or withdraw completed risk evaluations, determinations, and rules that were developed prior to the policies and procedures being finished.

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 3/2/2016 10:15:42 PM

To: 'Foster, Lakecia (Durbin)' [Lakecia_Foster@durbin.senate.gov]

Subject: Sen. Durbin TA Request on draft Lead-Safe Housing for Kids Act

Attachments: MIR16129_XML.DOC

Kecia.

This responds to your technical assistance request on the draft lead paint bill.

Page 1, line 24-25: the term "in accordance with the best available science" is unclear as to what criteria EPA should use to update, e.g., health based?

Page 2, line 25-26: "require a risk assessment for all housing receiving Federal assistance" A risk assessment reflects current conditions only. Lead paint is not static; a hazardous condition could emerge the day after a clean risk assessment. Note that without regular (e.g., annual) followup checks, this is unlikely to result in reliable risk reduction.

Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]

Sent: Wednesday, March 02, 2016 1:40 PM
To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Sven- thanks for arranging the call. Here's the latest draft from leg counsel. It does not include the changes HUD made to this draft, which I am working on incorporating. The EPA section is under Sec. 3 and a reference in the GAO report. However, it does not include amending the lead-based paint definition. We were thinking of adding lead-contaminated paint under Section 3 with the other standards, but that may not be the way to go.

It would be helpful to get TA on directing the standard to be evaluated to see if should be updated based on the best available science.

If I could be get something before COB today, that would be great. Working on a tight timeline.

Thanks, Kecia

Lakecía Joster

Economic Policy Advisor U.S. Senator Richard J. Durbin Assistant Democratic Leader 711 Hart Senate Office Building From: Foster, Lakecia (Durbin)

Sent: Wednesday, March 02, 2016 10:07 AM **To:** Kaiser, Sven-Erik Kaiser.Sven-Erik@epa.gov

Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Great. Thanks!

Lakecia Foster

Economic Policy Advisor U.S. Senator Richard J. Durbin Assistant Democratic Leader 711 Hart Senate Office Building 202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser, Sven-Erik@epa.gov]

Sent: Wednesday, March 02, 2016 10:06 AM

To: Foster, Lakecia (Durbin) < <u>Lakecia Foster@durbin.senate.gov</u>> **Subject:** Re: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia- let's have a call at 1pm. Please call 866-299-3188, code 202-566-2753#. Please let me know if any questions.

Thanks, Sven

On Mar 2, 2016, at 9:57 AM, Foster, Lakecia (Durbin) < <u>Lakecia Foster@durbin.senate.gov</u>> wrote:

Sven-Yes! I'm available between 10-11 am and between 11:30-1:30. If these time's don't work, I can find another time.

Thanks for your quick turnaround on this.

Lakecia Foster

Economic Policy Advisor U.S. Senator Richard J. Durbin Assistant Democratic Leader 711 Hart Senate Office Building 202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Wednesday, March 02, 2016 9:51 AM

To: Foster, Lakecia (Durbin) < <u>Lakecia Foster@durbin.senate.gov</u>> **Subject:** RE: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia – in response to your TA request on lead-based paint - any time available today for a quick phone call to discuss? We use different terms than the ones you indicate and I want to loop in key program folks to answer your questions. Thanks,

Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]

Sent: Tuesday, March 01, 2016 5:54 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Thanks.

We have some advocates that are interested in aligning the CPSC definition of lead-based paint with the one under the Lead-Based Paint Poisoning Prevention Act. I would like to know the difference in the definitions and why they are differ. I also would like to know what would be the impact of changing to the lower standard. Also, is there a difference between the definition and EPA's regulations on lead-contaminated paint?

We are finalizing text tomorrow for introduction on Thursday. Sorry for the late notice, but it is an issue that came up on my call with HUD today.

Thanks, Kecia

Lakecía Foster

Economic Policy Advisor U.S. Senator Richard J. Durbin Assistant Democratic Leader 711 Hart Senate Office Building 202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, March 01, 2016 3:44 PM

To: Foster, Lakecia (Durbin) < <u>Lakecia Foster@durbin.senate.gov</u>> **Subject:** Sen. Durbin Inquiry on lead-contaminated hazards

Lakecia,

Thanks for the inquiry about lead based paint hazards. Please let me know your questions and I'll be glad to provide a response or set up a call with our lead folks. Best, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia Foster@durbin.senate.gov]

Sent: Tuesday, March 01, 2016 2:30 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: EPA lead-contaminated hazards

Hi Sven,

My colleague, Jasmine Hunt, forwarded your contact information to me. I'm working on a bill regarding HUD lead regulations. We are also including related provisions that under EPA's jurisdiction. Do you have a moment to chat about the lead-based paint definition and EPA's regulations on lead-contaminated paint?

Thanks, Kecia

Lakecia Foster

Economic Policy Advisor U.S. Senator Richard J. Durbin Assistant Democratic Leader 711 Hart Senate Office Building 202-224-2152

Title: To amend the Residential Lead-Based Paint Hazard Reduction Act of 1992 to define 1 2 environmental intervention blood lead level, and for other purposes. 3 4 Be it enacted by the Senate and House of Representatives of the United States of America in 5 6 Congress assembled. SECTION 1. SHORT TITLE. 7 This Act may be cited as the ["Lead-Safe Housing for Kids Act of 2016"]. 8 SEC. 2. DEFINITIONS. 9 In this Act— 10 (1) the term "Department" means the Department of Housing and Urban Development; 11 (2) the term "housing receiving Federal assistance" has the meaning given the term in 12 section 35.110 of title 24. Code of Federal Regulations, or any successor thereto: 13 (3) the term "public housing agency" means an agency described in section 3(b)(6) of the 14 15 United States Housing Act of 1937 (42 U.S.C. 1437a(b)(6)); (4) the term "residential dwelling" has the meaning given the terms in section 1004 of the 16 Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4851b); and 17 (5) the term "Secretary" means the Secretary of Housing and Urban Development. 18 SEC. 3. UPDATES TO LEAD-CONTAMINATED DUST AND 19 LEAD-CONTAMINATED SOIL STANDARDS. 20 (a) EPA Regulations.—The Administrator of the Environmental Protection Agency, in 21 consultation with the Director of the Centers for Disease Control and Prevention, shall 22 promulgate regulations to update the standards for lead-contaminated dust and lead-contaminated 23 soil under part 745 of title 40, Code of Federal Regulations, in accordance with the best available 24 25 science. (b) HUD Regulations.—The Secretary shall promulgate regulations to update the standards for 26 27 lead-contaminated dust and lead-contaminated soil under part 35 of title 24, Code of Federal Regulations, in accordance with the regulations promulgated by the Administrator of the 28 Environmental Protection Agency under subsection (a). 29 SEC. 4. AMENDMENTS TO RESIDENTIAL LEAD-BASED 30 PAINT HAZARD REDUCTION ACT OF 1992. 31 (a) In General.—Section 1017 of the Residential Lead-Based Paint Hazard Reduction Act of 32 1992 (42 U.S.C. 4852c) is amended— 33 (1) by striking "Not later than" and inserting "(a) In General.—Not later than"; and 34 (2) by adding at the end the following: 35

1

"(b) Environmental Intervention Blood Lead Level.—

36

1 2	"(1) IN GENERAL.—For purposes of this title and any regulations issued under this title, an environmental intervention blood lead level means the lower of—
3	"(A) 5 ug/dL (micrograms of lead per deciliter);
4 5 6 7	"(B) the blood level reference value based on the 97.5th percentile of the population blood lead level in children ages 1 through 5 in the National Health and Nutrition Examination Survey and as recommended by the Centers for Disease Control and Prevention; or
8 9	"(C) the most recent definition for elevated blood lead level set by the Centers for Disease Control and Prevention.
10 11 12	"(2) RELATION TO OTHER AUTHORITIES.—Nothing in this Act may be construed to affect the authority of the Environmental Protection Agency under section 403 of the Toxic Substances Control Act (15 U.S.C. 2683)."
13 14 15	(b) Regulations.—Not later than 90 days after the date of enactment of this Act, the Secretary shall amend the regulations of the Department to comply with the amendments made by subsection (a).
16 17	SEC. 5. AMENDMENTS TO THE LEAD-BASED PAINT POISONING PREVENTION ACT.
18 19	Section 302(a) of the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. 4822(a)) is amended by adding at the end the following:
20	"(5) ADDITIONAL PROCEDURES FOR FAMILIES WITH CHILDREN UNDER THE AGE OF $6.$ —
21	"(A) RISK ASSESSMENT.—
22 23 24	"(i) IN GENERAL.—Not later than 90 days after the date of enactment of the [Lead-Safe Housing for Kids Act of 2016], the Secretary shall promulgate final regulations that—
25 26 27 28 29	"(I) require a risk assessment for all housing receiving Federal assistance described in paragraph (1) with respect to an initial inspection of a dwelling unit constructed prior to 1978 for lead-based paint and lead-based paint hazards prior to the occupancy by a family with a child of less than 6 years of age; and
30 31	"(II) provide that a visual assessment is not sufficient for purposes of complying with clause (i).
32 33 34 35	"(ii) EXCEPTION.—The final regulations promulgated under clause (i) shall provide an exception to the requirement under subclause (I) of such clause for dwelling units where the owner of the dwelling unit provides the Secretary with a certification or other proof that the dwelling unit is lead-free.
36 37 38 39	"(B) RELOCATION.—Not later than 90 days after the date of enactment of the [Lead-Safe Housing for Kids Act of 2016], the Secretary shall promulgate final regulations to provide that a family with a child of less than 6 years of age that occupies a dwelling unit in housing receiving Federal assistance described in paragraph (1) may relocate on

1 2	an emergency basis and without placement on any waitlist to another such dwelling unit without penalty or lapse in assistance if—
3	"(i) lead-based hazards were identified in the dwelling unit; or
4	"(ii)(I) lead-based hazards were identified in the dwelling unit; and
5 6 7	"(II) the environmental intervention blood lead level for the child exceeds the value described in section 1017(b) of the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4852c(b))."
8	SEC. 6. GAO REPORT ON LEAD HAZARDS IN
9	FEDERALLY ASSISTED HOUSING.
10 11	Not later than 180 days after the date of enactment of this Act, the Secretary shall submit to Congress a report on lead hazards in housing receiving Federal assistance, which shall—
12	(1) analyze the implications of—
13 14	(A) changing Department regulations to align with the Centers for Disease Control and Prevention standards; and
15 16 17 18 19	(B) requiring a risk assessment (beyond a visual assessment) for initial and periodic inspections for lead hazards for all housing receiving Federal assistance, primarily residential dwellings receiving assistance under section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f), and the impact it would have on landlord participation and the stock of affordable housing;
20 21	(2)(A) evaluate whether the current definition of lead-based paint is in accordance with the best available science; and
22 23	(B) provide recommendations to the Environmental Protection Agency on updating the relevant standards of that agency;
24 25 26 27	(3) analyze whether existing Federal programs and Federal funding for lead abatement activities in housing receiving Federal assistance meet the current and evolving needs, and if not, the merits of identifying or creating set-asides within those Federal programs to conduct lead abatement activities;
28 29 30 31	(4) evaluate the cost of lead prevention and abatement activities and provide recommendations on how to improve coordination and leveraging of public and private funds, including private investments and tax incentives, to reduce the cost associated with the identification and remediation of lead hazards and expedite home remediation;
32 33 34 35	(5) identify existing partnerships with public housing agencies and public health agencies in addressing lead hazards, what gaps exist in compliance and enforcement, and whether the partnerships can be replicated and enhanced with dedicated funding and better data collection and dissemination among stakeholders; and
36 37 38 39	(6) examine the appropriateness and efficacy of existing Department protocols on reducing or abating lead hazards and whether they are aligned with specific environmental health scenarios to ensure the best and appropriate health outcomes and reduce further exposure.

1 SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

- There is authorized to be appropriated to carry out this Act and the amendments made by this
- 3 Act such sums as may be necessary for each of fiscal years 2017 through 2021.

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/15/2016 6:00:19 PM

To: Adrian_Deveny@merkley.senate.gov
Subject: Sen. Merkley TSCA TA on state waiver.

Adrian,

This responds to the request on state preemption waivers.

Can EPA please take a look at the language in red below. The objective of this language is to a provide the opportunity for a state to obtain a waiver from pause pre-emption when essentially when the state has initiated its own rulemaking process to restrict a chemical prior to EPA. Some states do this with one rulemaking, and others do it with multiple rules in sequence, but the idea is that if a state has published a draft/proposed rule to prioritize a chemical prior to the start of the pause, then the final rule that does restrict the chemical can obtain an automatic waiver to be implemented during the pause.

First, does this language accomplish this objective?

No, because it doesn't clearly account for the fact that there are two different actions at issue: First, there is the action for which the state is seeking a preemption waiver; Second, there is the proposed or final *preliminary* action that predated EPA's scope publication, which is the basis for the state being entitled to the preemption waiver. What links the actions is that they relate to the same chemical substance, but there is no such linking language in the current draft. Also, the reference to a "draft" action should really be a reference to a "proposed" action. Here's the revised language, in context:

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

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(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on such chemical substance in accordance with section 6(b)(4)(D), that is for the prioritization, assessment, or management of such chemical substance or is otherwise related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.

Second, if I strike the words "for prioritization, assessment, management or other action", would it achieve the same objective? (allowing precursor draft/final rules on prioriziation and assessment completed before EPA's scoping to provide a waiver from the puase to the final state rule to restrict a chemical)

Deleting the words would make the passage less likely to function in the manner you intend. The phrase "prioritization, assessment, or management" helps to illustrate what you mean by an action

that is "related to the effects of exposure." Even though the illustrative list is just a subset of what is already included under the heading of "related to," an illustrative list helps to guard against courts later construing "related to" more narrowly than you intend (e.g., deciding that prioritization can't be related to the effects of exposure because the state hasn't yet definitively figured out what those effects are at the stage of prioritization).

Section 18(f)(2) Required Exemptions.—

- "(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—
 - "(A) (i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;
 - "(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and
 - "(iii)the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or
 - (B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action on a chemical substance for prioritization, assessment, management, or other action related to the effects of exposure to the chemical substance prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on the chemical substance in accordance with section 6(b)(4)(D), and has submitted such draft or final action to the Administrator."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

202-566-2753

From: "Deveny, Adrian (Merkley)" < Adrian Deveny@merkley.senate.gov>

Date: April 14, 2016 at 9:44:32 PM EDT

To: "Kaiser, Sven-Erik" < Kaiser. Sven-Erik@epa.gov>

Subject: TA on waiver

Sven

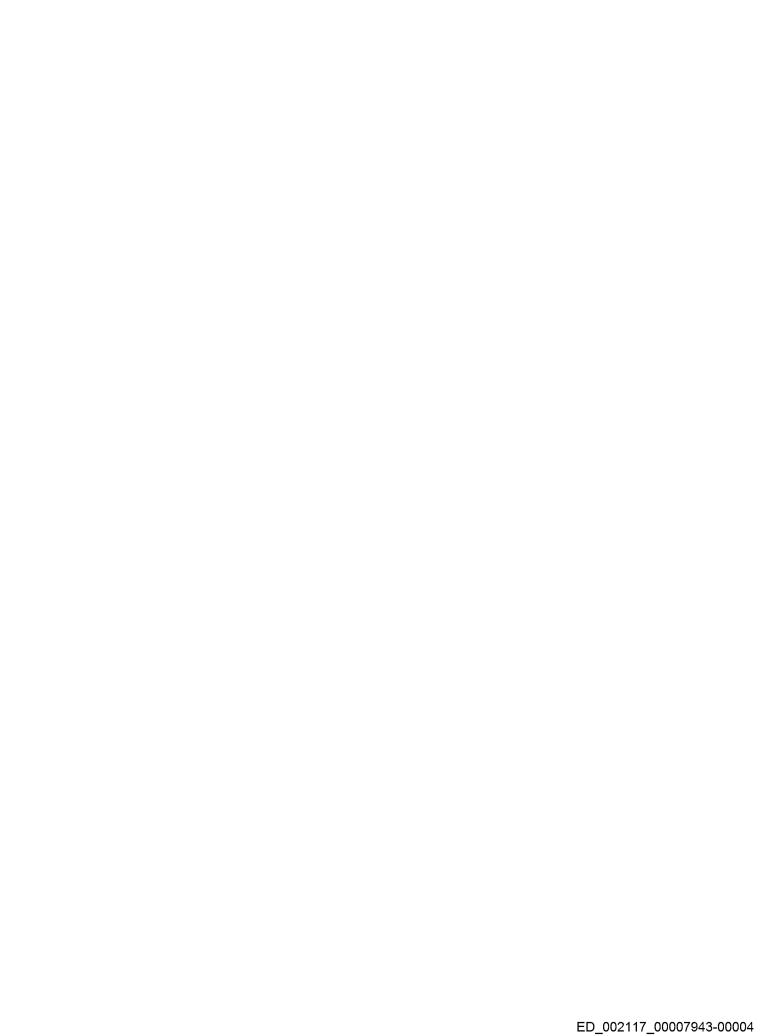
Can EPA please take a look at the language in red below. The objective of this language is to a provide the opportunity for a state to obtain a waiver from pause pre-emption when essentially when the state has initiated its own rulemaking process to restrict a chemical prior to EPA. Some states do this with one rulemaking, and others do it with multiple rules in sequence, but the idea is that if a state has published a draft/proposed rule to prioritize a chemical prior to the start of the pause, then the final rule that does restrict the chemical can obtain an automatic waiver to be implemented during the pause.

First, does this language accomplish this objective?

Second, if I strike the words "for prioritization, assessment, management or other action", would it achieve the same objective? (allowing precursor draft/final rules on prioriziation and assessment completed before EPA's scoping to provide a waiver from the puase to the final state rule to restrict a chemical)

Section 18(f)(2) Required Exemptions.—

- "(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—
 - "(A) (i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;
 - "(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and
 - "(iii)the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or
 - (B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action on a chemical substance for prioritization, assessment, management, or other action related to the effects of exposure to the chemical substance prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on the chemical substance in accordance with section 6(b)(4)(D), and has submitted such draft or final action to the Administrator."



From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/5/2016 6:39:24 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Deveny, Adrian (Merkley)

[Adrian Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan Black@tomudall.senate.gov]

Subject: RE: section 4

Michal – got it – thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Tuesday, April 05, 2016 2:34 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Cc: Karakitsos, Dimitri (EPW) < Dimitri_Karakitsos@epw.senate.gov>; Deveny, Adrian (Merkley)

<adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>

Subject: section 4

Sven

Attached is a new Section 4 that we need TA on. Generally, it can be described as:

- Existing TSCA 4(a)(1) and 4(a)(2) (mostly)
- In addition to that, Senate text on other circumstances that allow testing, by rule or order or consent agreement
- Other changes to things like ITC and 4(f) that have been discussed/proposed by various parties
- All (I hope) the conforming changes the House offer removed or didn't do

Please give it a careful read and let us know of any issues.

Senate colleagues – note I did not strike and replace the animal testing language but just bracketed it to reflect ongoing discussions. Let me know if you want a different approach there.

Thanks michal

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/13/2016 7:54:10 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: Sen. Markey TSCA TA on PBT - revised draft

Attachments: Markey. TSCA TA.PBT (4-12).docx

Michal – the attached TA responds to the request on the revised draft PBT language.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Tuesday, April 12, 2016 8:38 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: Sen. Markey TSCA TA on PBT - revised draft

Can you suggest a way to assist on the first question? I am trying as hard as I can to get you fees for exposure assessments, I'm definitely not ignoring that concern.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey









From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, April 12, 2016 6:57 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA on PBT - revised draft

Michal.

This TA responds to the follow up request on PBTs.

We reviewed the attached revised version and still have a difficult time understanding how EPA would be expected to operate under this provision. The language makes clear that for identified PBTs, EPA would propose rules that both protect against unreasonable risks and "reduce exposure to the extent practicable." The language also states that risk evaluations are <u>not</u> required for the identified chemicals. We see the two statements as irreconcilable. EPA determines "unreasonable risk" by doing a risk evaluation on a chemical. Without knowing whether and how the chemical presents an "unreasonable risk," EPA would be unable to draft a rule "in accordance with subsection (a)."

We'd also note that in the absence of risk evaluation under Section 6, there's no associated fee collection authority under Section 26.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Tuesday, April 12, 2016 3:02 PM

To: Kaiser, Sven-Erik < <u>Kaiser.Sven-Erik@epa.gov</u> > **Subject:** 04-12-16PBT (Conf Proposal)d.docx

See if this works on pbts

ALL CITATIONS AND CROSS-REFERENCES ARE TO SECTION 6 AS IT APPEARS IN THE SENATE OFFER

- () Chemicals That Are Persistent, Bioaccumulative, and Toxic.--
- (1) Expedited Action.--Not later than Laurenberg Chemical Safety for the 21st Century Act, the Administrator shall propose a rules under the accordance with subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments
 - (A) that the Administrator has a reasonable basis to conclude are toxic and with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under section 4 prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and
 - (B) exposure to which under the conditions of use is likely to the general population, a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator
- (2) Prior to issuing the proposed rules required by paragraph (1), the Administrator shall conduct risk evaluations for the subject chemical substances pursuant to section 6(b)(4), except that section 6(b)(4)(H) shall not apply. Such risk evaluations shall count toward the number of risk evaluations required to be conducted under section 6(b)(2). Except as provided in paragraph (5), the Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to this subsection.
- (3) Final Rules.--Notwithstanding subsections (__), subject to subsections __ and __, not later than 18 months after proposing a-rules under paragraph (1), the Administrator shall promulgate finals rules under in accordance with subsection (a).
- (4) Each proposed and final rule required by paragraphs (1) and (3) shall be developed in accordance with section 6(c)(2) (3) and (4). Each such proposed and final rule shall ensure that the subject chemical substance does not present any unreasonable risk of injury to health or the environment that the Administrator determines the chemical substance presents in the risk evaluation under section 6(b)(4), and shall reduce exposure to the substance to the extent practicable. In selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a) the Administrator shall, for each chemical substance for which a rule is proposed under paragraph (1), reduce exposure to the substance to the extent practicable.
- (5) Alternative approach Relationship to subsection (b). Within 3 months (?) of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall

Commented [A1]: This is based on three years for the risk evaluation (the timeframe allowed in section 6(b)(4)(G)(i) of senate offer, without the opportunity to extend by a year afforded in (G)(ii), plus one year for the proposal, per sec 6(c)(1)(A), without the opportunity to extend afforded in 6(c)(3).

Commented [A2]: Presumably EPA is not required to address these chemicals in a single rulemaking, so long as EPA meets the 4-year deadline.

Commented [A3]: This is the requirement for notice and comment on risk evaluations.

Formatted: Highlight

Commented [A4]: This subjects these rulemakings to the required consideration provisions (including cost) and articles and replacement part provisions for 6(a) rules (6(c)(2)), and the rulemaking procedure provision (6(c)(3) and (4)). It does not include the deadline provision (6(c)(1)) because deadlines are handled in this provision.

NOTE TO EPA REVIEWERS: An argument could be made that EPA should not be saddled with all of the 6(c)(2) requirements under a rule where we are merely reducing exposure. Eg, it is not clear why EPA could consider the effects of the substance on health and the environment, and factor those considerations in to the selection of restrictions, under such a rule. That said, it seems more complicated than it's trying to apply (c) to one set of rules and not another.

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identify the chemical substances that are subject to paragraph (1). If, within 3 months (?) of such identification at any time prior to the date that is 90 days after the date on which the Administrator proposes the rule under paragraph (1), the Administrator makes a finding under subsection (____), or a manufacturer requests a risk evaluation under subsection (____), with respect to such a chemical substance, such chemical substance shall not be subject to this subsection, except that any proposed or final rule promulgated in accordance with section 6(a) for such chemical substance shall ensure that the chemical substance does not present an unreasonable risk of injury to health or the environment and reduce exposure to the substance to the extent practicable.

(5) OTHER CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC OR CARCINOGENS.—

- (A) In designating high priority substances pursuant to subsection (b), the Administrator shall give preference to—
- chemical substances that, with respect to persistence and bioaccumulation, score high for 1
 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals
 Methods Document published by the Administrator in February 2012 (or a successor
 scoring system); and
- (ii) chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.
- (B) In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.
- (C) For a chemical substance subject to subsection (a) that with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system) the proposed and final rules shall Administrator shall—ensure that the chemical substance does not present an unreasonable risk of injury to health or the environment and reduce exposure to the substance to the extent practicable, in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), reduce exposure to the substance to the extent practicable.

Retain expedited action provision in 6(c)

(C) may extend the deadlines under this paragraph for not more than two years, subject to the condition that the aggregate length of extensions under this paragraph and subsection (b)(4)(G) does not exceed two years, and subject to the limitation that the Administrator may not extend a deadline for the

Commented [A5]: How will they know? Could drop this Formatted: Highlight

Commented [A6]: As edited, this provision now just removes these PBTs from the front of the queu.

Commented [A7]: As edited, this provision now just removes these PBTs from the front of the queue.

publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

Commented [A8]: This will not apply to PBTs subject to expedited action under (1), because that provides its own deadline, which would not be extended by this provision allowing extension of 6(c) deadlines. Extension authority for these chems would have to be provided in this PCB section—could be relatively easily drafted if desired.

In addition, some conforming changes in section 6 would need to be made or considered in view of this new PBT provision. The parenthetical phrase addressing PBTs at the end of section 6(b)(2)(A) presumably should be stricken, since this new PBT provision establishes a stronger priority for PBTs. Also, consider whether the parenthetical at the end of 6(b)(2)(B) re PBTs should be dropped, on the grounds that there will not be enough PBTs left to fill the 50% quota. Also, 6(b)(2)(D)(i) may be obsolete for a similar reason.

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 2/24/2016 4:39:05 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: Sen. Markey TSCA TA request - section 12

Michal – got it - thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Wednesday, February 24, 2016 11:33 AM **To:** Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: TA request - section 12

Sven

Other than fixing the "unreasonable risks" in section 12 (and the Hg language added en route to the Floor), does EPA see any workability or other problems associated with leaving section 12 the way it is in existing statute rather than the changed version in 697?

Michal

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/28/2016 10:12:01 PM

To: Couri, Jerry [JerryCouri@mail.house.gov]

Subject: Re: TA request on TSCA section 5

Thanks- will do

On Apr 28, 2016, at 6:09 PM, Couri, Jerry < JerryCouri@mail.house.gov> wrote:

As soon as you can. Tomorrow morning at the latest.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Thursday, April 28, 2016 6:06 PM

To: Couri, Jerry

Subject: Re: TA request on TSCA section 5

Jerry- got it- checking. How soon needed? Thanks,

Sven

On Apr 28, 2016, at 5:53 PM, Couri, Jerry < JerryCouri@mail.house.gov> wrote:

Sven:

Thanks to you and the folks at EPA for the TA on section 5. We have a follow-up question on what you sent to us:

If we change the wording in proposed new section 5(a)(3)(B) to match existing section 5(e) -- as I think the Agency's TA suggests, would we need to change the lead in to existing 5(e)?

Thanks.

<!--[if !supportLists]--><!--[endif]-->Jerry

Gerald S. Couri

Senior Environmental Policy Advisor | Committee on Energy and Commerce

U.S. House of Representatives

2125 Rayburn Building | 202.226.9603 (direct)

<image001.png><image002.png><image003.png><image004.png><image005.png>

Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From:

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 3/17/2016 11:31:12 AM

Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov] To: Subject: Re: Sen. Markey TSCA TA Request on Section 6 cost considerations

Michal - this got put on the side. Will get it going pronto. Thanks, Sven

On Mar 17, 2016, at 5:45 AM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

Good morning

It is possible we will start a section 6 discussion today. Is this getting close?

Μ

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik

Sent: Tuesday, March 8, 2016 11:21 AM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA Request on Section 6 cost considerations

Michal – got it (late catch). Thanks,

Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Monday, March 07, 2016 2:22 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov> Subject: TA request - Section 6 cost considerations

In the same spirit and on the same timeframe as the others I've sent today, can this redline to what was sent to the House last week AND the version of the language that was sent to the House last week be ranked/added to the table from the 01/05/16 TA?

Thanks Michal

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/19/2016 10:12:46 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley)

[Adrian Deveny@merkley.senate.gov]

Subject: TSCA TA: follow up re section 5 - "or otherwise necessary"

Michal, Jonathan, and Adrian,

We understand that the question is whether the phrase "or as otherwise necessary" should be inserted after "submitter."

We just spoke to Dmitri, Richard Denison and Mike Walls about this. We do not think this addition is necessary, since EPA would have no need to unilaterally extend the review period to require testing. If the submitter does not agree to an extension, then the review period would lapse without and (a)(3)(A) determination or an (e) order, and manufacture and processing could not commence.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Tuesday, April 19, 2016 4:41 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley)

<Adrian_Deveny@merkley.senate.gov> **Subject:** as a follow up re section 5

We specifically want your view on the following change

Page 8 line 5 – Insert "or as otherwise necessary" after "matter[Z1] [Z2] "

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey









From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 3/2/2016 6:43:08 PM

To: 'Foster, Lakecia (Durbin)' [Lakecia_Foster@durbin.senate.gov]

Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia – thanks for sending over the TA request. I'll see what we can get you tonight. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]

Sent: Wednesday, March 02, 2016 1:40 PM **To:** Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Sven- thanks for arranging the call. Here's the latest draft from leg counsel. It does not include the changes HUD made to this draft, which I am working on incorporating. The EPA section is under Sec. 3 and a reference in the GAO report. However, it does not include amending the lead-based paint definition. We were thinking of adding lead-contaminated paint under Section 3 with the other standards, but that may not be the way to go.

It would be helpful to get TA on directing the standard to be evaluated to see if should be updated based on the best available science.

If I could be get something before COB today, that would be great. Working on a tight timeline.

Thanks, Kecia

Lakecia Joster

Economic Policy Advisor U.S. Senator Richard J. Durbin Assistant Democratic Leader 711 Hart Senate Office Building 202-224-2152

From: Foster, Lakecia (Durbin)

Sent: Wednesday, March 02, 2016 10:07 AM **To:** Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Great. Thanks!

Lakecia Foster

Economic Policy Advisor

U.S. Senator Richard J. Durbin Assistant Democratic Leader 711 Hart Senate Office Building 202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Wednesday, March 02, 2016 10:06 AM

To: Foster, Lakecia (Durbin) < <u>Lakecia Foster@durbin.senate.gov</u>> **Subject:** Re: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia- let's have a call at 1pm. Please call 866-299-3188, code 202-566-2753#. Please let me know if any questions.

Thanks, Sven

On Mar 2, 2016, at 9:57 AM, Foster, Lakecia (Durbin) < Lakecia_Foster@durbin.senate.gov> wrote:

Sven-Yes! I'm available between 10-11 am and between 11:30-1:30. If these time's don't work, I can find another time.

Thanks for your quick turnaround on this.

Lakecía Foster

Economic Policy Advisor U.S. Senator Richard J. Durbin Assistant Democratic Leader 711 Hart Senate Office Building 202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Wednesday, March 02, 2016 9:51 AM

To: Foster, Lakecia (Durbin) < <u>Lakecia Foster@durbin.senate.gov</u>> **Subject:** RE: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia – in response to your TA request on lead-based paint - any time available today for a quick phone call to discuss? We use different terms than the ones you indicate and I want to loop in key program folks to answer your questions. Thanks,

Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]

Sent: Tuesday, March 01, 2016 5:54 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Thanks.

We have some advocates that are interested in aligning the CPSC definition of lead-based paint with the one under the Lead-Based Paint Poisoning Prevention Act. I would like to know the difference in the definitions and why they are differ. I also would like to know what would be the impact of changing to the lower standard. Also, is there a difference between the definition and EPA's regulations on lead-contaminated paint?

We are finalizing text tomorrow for introduction on Thursday. Sorry for the late notice, but it is an issue that came up on my call with HUD today.

Thanks, Kecia

Lakecía Foster

Economic Policy Advisor U.S. Senator Richard J. Durbin Assistant Democratic Leader 711 Hart Senate Office Building 202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, March 01, 2016 3:44 PM

To: Foster, Lakecia (Durbin) < <u>Lakecia Foster@durbin.senate.gov</u>> **Subject:** Sen. Durbin Inquiry on lead-contaminated hazards

Lakecia,

Thanks for the inquiry about lead based paint hazards. Please let me know your questions and I'll be glad to provide a response or set up a call with our lead folks. Best, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]

Sent: Tuesday, March 01, 2016 2:30 PM

To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>

Subject: EPA lead-contaminated hazards

Hi Sven,

My colleague, Jasmine Hunt, forwarded your contact information to me. I'm working on a bill regarding HUD lead regulations. We are also including related provisions that under EPA's jurisdiction. Do you have a moment to chat about the lead-based paint definition and EPA's regulations on lead-contaminated paint?

Thanks, Kecia

Lakecia Foster

Economic Policy Advisor U.S. Senator Richard J. Durbin Assistant Democratic Leader 711 Hart Senate Office Building 202-224-2152

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/15/2016 5:02:04 PM

To: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]

Subject: Re: Sen. Merkley TSCA TA request on waiver

Adrian- thanks for the reminder. We're working on it and should have something for you shortly. Best, Sven

On Apr 15, 2016, at 1:00 PM, Deveny, Adrian (Merkley) < Adrian Deveny@merkley.senate.gov > wrote:

Sven-. Any progress here? We need this today.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik

Sent: Thursday, April 14, 2016 9:52 PM

To: Deveny, Adrian (Merkley)

Subject: Sen. Merkley TSCA TA request on waiver

Adrian,

Thanks for the TA request. I'll get it to folks to get a response. Please let me know if any additional questions. Thanks,

Sven

On Apr 14, 2016, at 9:44 PM, Deveny, Adrian (Merkley) < Adrian Deveny@merkley.senate.gov > wrote:

Sven

Can EPA please take a look at the language in red below. The objective of this language is to a provide the opportunity for a state to obtain a waiver from pause pre-emption when essentially when the state has initiated its own rulemaking process to restrict a chemical prior to EPA. Some states do this with one rulemaking, and others do it with multiple rules in sequence, but the idea is that if a state has published a draft/proposed rule to prioritize a chemical prior to the start of the pause, then the final rule that does restrict the chemical can obtain an automatic waiver to be implemented during the pause.

First, does this language accomplish this objective?

Second, if I strike the words "for prioritization, assessment, management or other action", would it achieve the same objective? (allowing precursor draft/final rules on prioriziation and assessment completed before EPA's scoping to provide a waiver from the puase to the final state rule to restrict a chemical)

Section 18(f)(2) Required Exemptions.—

- "(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—
 - "(A) (i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;
 - "(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

- "(iii)the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or
- (B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action on a chemical substance for prioritization, assessment, management, or other action related to the effects of exposure to the chemical substance prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on the chemical substance in accordance with section 6(b)(4)(D), and has submitted such draft or final action to the Administrator."

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/24/2016 1:13:14 AM

To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov; Adrian_Deveny@merkley.senate.gov

Subject: Sen. Markey TSCA TA on House section 6 (4-22)

Attachments: Markey.TSCA TA.House Section 6 (4-22).docx; ATT00001.htm

Michal,

This TA responds to the request on House section 6 (4-22).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

We have just one bit of TA on the April 22 HLC draft of section 6:

Complex consumer goods are now defined as having multiple parts, not 50 parts. Since this would mean that electronic or mechanical devices with 2 or more parts fall within the definition, one may as well drop the numerical criterion.

Here are some additional observations about this version, which we point out but have no technical concerns with. The draft:

- -- Drops from 6(a) the reference to PBTs, thereby avoiding potential confusion about the rulemaking standard.
- -- Makes both active and inactive substances subject to prioritization
- -- Makes low priority dependent on a "likely not to present" finding
- -- Strikes much of (b)(2)(C), which had provided direction for continuing prioritization and risk evaluation after 3-1/2 years; the dropping of this text eliminates the provision requiring that all work plan chemicals undergo risk evaluation, and the awkwardness of prioritizing with a foreordained outcome.
- -- Retains the requirement for EPA to do a prioritization rule, but eliminates the requirement for notice and comment in prioritization and the required deadlines for prioritization
- -- Strikes the requirement for notice and comment on industry requests for risk evaluations
- -- Drops the specification that EPA must consider quantified and unquantified costs and benefits in rulemaking, and just instructs EPA to consider costs and benefits
- -- Includes 6(c)(2)(C) -- the provision that requires EPA to consider whether feasible alternatives are available in deciding whether to ban or severely restrict and that had been dropped from the preceding draft. The consideration is now limited "to the extent practicable", which had not been in the previous version
- -- Amends 6(c)(2)(E) to make it easier for EPA to regulate articles. EPA must show that such regulation is necessary to address identified risks, but need not show that the risks come from the article or category of articles.

We are not troubled by the elimination of required timeframes for prioritization, or by the dropping of the requirement in (b)(2)(C) to keep prioritizing and evaluating until the priority of

all active substances has been designated, because we think continued throughput is secured by the following provisions:

- The requirement to have at least 20 high-priority substances undergoing risk evaluation within 3-1/2 years in (b)(2)(B),
- The deadlines for risk evaluations ((b)(4)(G)) and the requirement to initiate risk evaluation "upon designating a chemical substance as high-priority" ((b)(3)(A)), and
- The requirement to add a high-priority chemical for each completion of a risk evaluation on a high-priority chemical ((b)(3)(C)).

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/5/2016 5:44:55 PM

To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]

Subject: Re: SEPW TSCA TA call on CBI

Got it

On Apr 5, 2016, at 1:42 PM, Black, Jonathan (Tom Udall) < <u>Jonathan Black@tomudall.senate.gov</u>> wrote:

Scrap this request, as mentioned on today's phone call. We are sending something else.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Black, Jonathan (Tom Udall)
Sent: Tuesday, April 5, 2016 9:14 AM
To: Kaiser.Sven-Erik@epamail.epa.gov
Subject: FW: SEPW TSCA TA call on CBI

Sven, Dimitri shared these views with me, which is helpful.

I saw earlier EPA TA on the intro's to subsection (b) and others. I believe we've taken a stab at reworking it. not sure if Michal has run it by you yet, but wondering if it alleviates the earlier concerns.

<image001.png>

From: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Sent: Monday, April 4, 2016 10:13 PM

To: Karakitsos, Dimitri (EPW)

Subject: Re: SEPW TSCA TA call on CBI

Dimitri- we're fine with the language. It works and looks consistent with our TA. Please let me know if any questions.

Thanks, Sven

On Apr 4, 2016, at 5:01 PM, Karakitsos, Dimitri (EPW) < Dimitri Karakitsos@epw.senate.gov > wrote:

Sven – just wanted to send this to you to confirm from the call that this works and would be consistent with previous TA as well as TA from the call. Thanks

(1) OTHER INFORMATION NOT PROTECTED FROM

DISCLOSURE Subsection (a) does not prohibit the disclosure of

- (A) A risk evaluation conducted under section 6.
- (B) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.
- (C) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry

or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL

INFORMATION.—Any information that is eligible for protection under this section, that is not information described in subsections (c)(1) or (c)(2) or information required to be disclosed through subsection (c)(4) and is submitted with or contained in information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Monday, April 04, 2016 3:39 PM

To: Karakitsos, Dimitri (EPW)
Subject: SEPW TSCA TA call on CBI

Dimitri – 4 is the earliest we can do it -- please call Ex. 6 - Personal Privacy | Code | Ex. 6 - Personal Privacy | Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri Karakitsos@epw.senate.gov]

Sent: Monday, April 04, 2016 3:31 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov >

Subject: RE: can we do a quick

Yup that should be fine, if you all want to call and can any earlier I will be here.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Monday, April 04, 2016 3:31 PM

To: Karakitsos, Dimitri (EPW) **Subject:** RE: can we do a quick

Dimitri - Checking - I think we can do 4pm - ok?

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri Karakitsos@epw.senate.gov]

Sent: Monday, April 04, 2016 3:29 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov >

Subject: can we do a quick

5 min call on this cbi paragraph when you get a chance please? I am available now if your folks are and can be reached at my desk – 224-9705

(1) MIXED CONFIDENTIAL AND NONCONFIDENTIAL

INFORMATION.—Any information that is eligible for protection under this section, that is not information described in subsections (c)(1) or (c)(2) or information described in subsection (c)(4) for which the protection from disclosure is presumed to no longer apply, and is submitted with or contained in information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/13/2016 7:18:13 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: RE: Sen. Markey TSCA TA request on section 6

Got it - thanks

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Wednesday, April 13, 2016 3:16 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov > **Subject:** RE: Sen. Markey TSCA TA request on section 6

Do PBT, 5, 6, THEN 14

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey









From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Wednesday, April 13, 2016 3:15 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA request on section 6

Michal – thanks for the request on section 6. Timing? We've got PBT, 5 and 14 in the queue. Best, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Wednesday, April 13, 2016 3:13 PM

To: Kaiser, Sven-Erik < Kaiser.Sven-Erik@epa.gov>

Subject: section 6

Sven

This is HLC section 6. Pls take a look.

Thanks

Μ

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 2/24/2016 4:35:49 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: Sen. Markey TSCA TA Request - Section 8/14 - false claims on CBI

Michal, Got it. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Wednesday, February 24, 2016 11:28 AM **To:** Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: Section 8/14 - false claims on CBI

Sven

Has EPA ever enforced against a company for making a false CBI claim?

Is there sufficient authority under 697 for EPA to do so? Does requiring companies to certify their CBI claims alter existing enforcement authority?

Thanks Michal

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/8/2016 8:24:53 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

Subject: Re: Sen. Markey TSCA TA request on PBTs

Got it - thanks

On Apr 8, 2016, at 4:12 PM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

Thanks. For context, we are working through the potential for a hybrid House-Senate PBT provision for section 6 that would downselect some of the high pbts from the TSCA workplan and send them straight to risk management. In addition to metals/metal compounds, there is a suggestion that these 3 should perhaps be excluded because EPA is already looking at them enough to basically be able to say "they've already done a bunch of what would go into the risk evaluation, so they should continue on the path they're on". That rationale seems perhaps to be solid for the first 2 – do you agree? What about the 3rd? would you need that data to go to risk management anyway?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Friday, April 08, 2016 4:06 PM **To:** Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA request on PBTs

Michal,

This responds to the TA request on PBTs.

Chlorinated paraffins:

The medium and long-chain chlorinated paraffins are being reviewed under Section 5. (Short-chain CPs have been taken off the market). Because of the high level of interest in these chemicals, EPA published an assessment in Dec. 2015 with a request for additional information on downstream uses of the chemicals. The comment period closed on March 23d, and we are currently reviewing comments.

HBCD:

EPA published a Work Plan Problem Formulation for comment in August 2015. We are developing a draft assessment and hope to publish this summer.

D4Siloxane:

We are not assessing at this time. We entered into an Enforceable Consent Agreement under section 4 to obtain monitoring and environmental fate data to inform an assessment. The work is underway now through fall to develop the data and we expect to receive it in 2017.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Friday, April 08, 2016 1:53 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: TA request on PBTs

Chlorinated paraffins HBCD D4siloxane

For these - I'm told EPA is doing risk assessment-like work on these. How far into the process are you for each of these?

Thx M

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA) From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 3/16/2016 11:38:50 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

Subject: Sen. Market TSCA TA on section 14(e)(9)

Michal- got it. Thanks, Sven

On Mar 16, 2016, at 7:08 PM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

<!--[if !supportAnnotations]--> <!--[endif]-->

You're recommending restoration of the text below

In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely—on

section 552(b)(3) of such title to sustain the Administrator's action.<!--[if!supportAnnotations]-->[MF1]<!--[endif]-->

But 14(a) says that EPA can't disclose anything that is exempt from disclosure under 552(a) of title 5 under exemption (b)(4).

If EPA can't release something that is FOIA-exempt under section 14, how would there be an instance in which EPA released something that would subsequently be withheld under FOIA? I'm just reading this as circular and am going to need to be able to explain it to others if I am going to be able to undo the deletion.

Thanks Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

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<!--[if !supportAnnotations]-->

<!--[endif]-->

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/19/2016 9:20:15 PM

To: Michal_Freedhoff@markey.senate.gov

Subject: TSCA TA request on revised House section 5 (4-18) **Attachments**: Section 5 (HLC) 4 18 26 OGC.docx; ATT00001.htm

Michal-revised house section 5 TA

This version addresses the comments we had on the version we sent out yesterday but introduces a number of new issues.

**This is a RLSO of Section 5, comparing HLC version timestamped <u>April 12, 2016 at 1:50pm</u> to HLC version timestamped <u>April, 18, 2016 at 3:38pm</u>.

[DISCUSSION DRAFT]

1	SEC. II. MANUFACTURING AND PROCESSING NOTICES.
2	Section 5 of the Toxic Substances Control Act (15
3	U.S.C. 2604) is amended—
4	(1) in subsection (a)—
5	(A) in paragraph (1)—
6	(i) by striking "Except as provided
7	in" and inserting "(A) Except as provided
8	in subparagraph (B) of this paragraph
9	and";
10	(ii) by redesignating subparagraphs
11	(A) and (B) as clauses (i) and (ii), respec-
12	tively;
13	(iii) by striking all that follows "sig-
14	nificant new use" and inserting a period;
15	and
16	(iv) by adding at the end the fol-
17	lowing:
18	"(B) A person may take the actions described
19	in subparagraph (A) if—
20	"(i) such person submits to the Adminis-
21	trator, at least 90 days before such manufac-
22	ture or processing, a notice, in accordance with

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1	subsection (d), of such person's intention to
2	manufacture or process such substance and
3	such person complies with any applicable re-
4	quirement of or imposed under subsection (b),
5	(e), or (f); and
6	"(ii) the Administrator conducts a review
7	of the notice and either—
8	"(I) makes a determination under
9	paragraph (3)(A) and, as necessary, issues
10	an order under subsection (f)(1); or
11	"(II) makes a determination under
12	paragraph (3)(B) and issues an order
13	under subsection (e)(1)(B)."; and
14	(B) by adding at the end the following new
15	paragraphs:
16	
17	"(3) Review and determination.—
18—	"Before the end of the applicable review period, which shall be the 90-day period for review under paragraph (1), subject to any extensions made pursuant to subsection (b), (c) or (e), and subject to section 18, the Adminstrator shall review a notice received under paragraph (1), and—"
19	Not later than 90 days after receipt of a notice under para-
20	graph (1), subject to section 18, the Administrator
21	shall review such notice and—
22	"(A) determine whether the relevant chem-
23	ical substance or significant new use may

Commented [GB1]: Seems like this should refer to the applicable review period, not the 90-day period, like SLC did. Isn't that the period in which the Admininstrator must do one of these things?

present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or sus-

1	ceptible subpopulation identified as relevant by
2	the Administrator under the conditions of use,
3	and take applicable action under subsection (f)
4	or (g); or
5	"(B) determine that additional information
6	is necessary to make the determination under
7	subparagraph (A), and take applicable action
8	under subsection (e).
9	"(4) FAILURE TO RENDER DETERMINATION.—
10	"(A) IN GENERAL.—The Administrator
11	shall complete a review of a notice required by
	this section within the applicable review period
12	"(BA) Failure to render determina-
13	TION.—If the Administrator fails to make a de-
14	termination on a notice under paragraph (3) by
15	the end of the applicable review period and the
16	notice has not been withdrawn by the sub-
17	mitter, the Administrator shall refund to the
18	submitter all applicable fees charged to the sub-
19	mitter for review of the notice pursuant to sec-
20	tion 26(b)(1), and the Administrator shall not
21	be relieved of any requirement to make such de-
22	termination.
23	"(ϵ B) Limitations.—(i) A refund of appli-
24	cable fees under subparagraph (A) shall not be
25	made if the Administrator certifies that the
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submitter has not provided information required

27 under subsections (b) or (e) or has otherwise

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1	unduly delayed the process such that the Ad-
2	ministrator is unable to render a determination
3	within the applicable period of review.
4	"(ii) A failure of the Administrator to
5	render a decision shall not be deemed to con-
6	stitute a withdrawal of the notice.
7	"(iii) Nothing in this paragraph shall be
8	construed as relieving the Administrator or the
9	submitter of the notice from any requirement of
10	this section.
11	"(5) ARTICLE CONSIDERATION.—The Adminis-
12	trator may require notification under this section for
13	the import or processing of a chemical substance as
14	part of an article or category of articles under para-
15	graph (1)(B) if the Administrator makes an affirma-
16	tive finding in a rule under paragraph (2) that the
17	reasonable potential for exposure to the chemical
18	substance through the article or category of articles
19	subject to the rule justifies notification.";
20	(2) in subsection (b)—
21	(A) in the subsection heading, by striking
22	"Test Data" and inserting "Information";
23	(B) in paragraph (1)—
24	(i) in subparagraph (A)—

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1	(I) by striking "test data" and
2	inserting "information"; and
3	(II) by striking "such data" and
4	inserting "such information"; and
5	(ii) in subparagraph (B), by striking
6	"test data" and inserting "information";
7	(C) in paragraph (2)—
8	(i) in subparagraph (A)—
9	(I) by striking "test data" and
10	inserting "information";
11	(II) by striking "shall" and in-
12	serting "may"; and
13	(III) by striking "data pre-
14	scribed" and inserting "information
15	prescribed"; and
16	(ii) in subparagraph (B)—
17	(I) by striking "Data" and in-
18	serting "Information";
19	(II) by striking "data" both
20	places it appears and inserting "infor-
21	mation"; and
22	(III) by striking "show" and in-
23	serting "shows";
24	(D) in paragraph (3)—

)

1	(i) by striking "Data" and inserting
2	"Information"; and
3	(ii) by striking "paragraph (1) or (2)"
4	and inserting "paragraph (1) or (2) of this
5	subsection or under subsection (e)"; and
6	(E) in paragraph (4)—
7	(i) in subparagraph (A)(i), by insert-
8	ing ", without consideration of costs or
9	other nonrisk factors" after "health or the
10	environment"; and
11	(ii) in subparagraph (C), by striking
12	", except that" and all that follows
13	through "subparagraph (A)";
14	(3) in subsection (c)—
15	(A) in the subsection heading, by inserting
16	"AND REVIEW" after "NOTICE"; and
17	(B) by striking "before which" and all that
18	follows through "subsection may begin";
19	(4) in subsection (d)—
20	(A) by striking "test data" in paragraph
21	(1)(B) and inserting "information";
22	(B) by striking "data" each place it ap-
23	pears in paragraph (1)(C) and paragraph (2)
24	and inserting "information";

7

1	(C) in paragraph (2)(B), by striking "uses
2	or intended uses of such substance" and insert-
3	ing "uses of such substance identified in the no-
4	tice and any additional uses of such substance
5	that are reasonably foreseeable by the Adminis-
6	trator"; and
7	(D) in paragraph (3)—
8	(i) by striking "for which the notifica-
9	tion period prescribed in subsection (a),
10	(b), or (c)" and inserting "for which the
11	applicable review period"; and
12	(ii) by striking "such notification pe-
13	riod" and inserting "such period";
14	(5) by amending subsection (e) to read as fol-
15	lows:
16	"(e) Regulation When Available Information
17	Is Insufficient.—(1) If the Administrator determines
18	that the information available to the Administrator is in-
19	sufficient to permit the Administrator to make a deter-
20	mination in accordance with subsection (a)(3)(A) for a
21	chemical substance or significant new use with respect to constant and respect to constant respect t
22	which notice is required by subsection (a)—
23	"(A) the Administrator—

1	"(i) shall provide an opportunity for the
2	submitter of the notice to submit the additional
3	information within the applicable review period;
4	"(ii) may, by agreement with the sub-
5	mitter, extend the applicable review period for
6	a reasonable time to allow the development and
7	submission of the additional information under
8	section 4; and
24	"(iii) may extend the applicable review period as necessary and promulgate a rule, enter into—a
25	consent agreement, or issue an order under sec-
26	tion 4 to require the development of the infor-
27	——mation; and
1	"(iv) on receipt of the additional informa-
2	tion the Administrator finds supports the deter-
3	mination under subsection (a)(3)(A), which shall automatically extend the review period for 90 days, shall
4	make the determination within 90 days of re-
5	ceipt of the information; and
1	(iii) on receipt of the additional informa-
2	tion complying with a rule, testing consent
3	agreement, or order issued under section 4,
4	may extend the review period not more than 90
5	days to make a decision; and
6	"(B) the Administrator may issue an order to
7	take effect on the expiration of the applicable review

Commented [GB2]: Not sure this is needed, since section 4 already provides for testing for this purpose, and this suggests that EPA and the applicant cannot by agreement extend the period to allow for the submitter to voluntarily develop information. But maybe that's intended, in which case this is fine.

Commented [GB3]: (ii) refers to "applicable" review period. Either formulation seems acceptable in this context, but should be consistent.

Commented [GB4]: (iii) is different from SLC in several ways. 1. It does not require EPA to make an (a)(3)(A) determination upon receipt of information, both because it merely allows EPA to extend upon receipt of info, and if EPA does extend, merely specifies that EPA "make a decision", not "make the determination under subsection (a)(3)(A)" as SLC specified. 2. The section 4 reference seems too limiting. Even if (ii) is limited to info development under sec 4, (i) seems to contemplate voluntary submission of additional information. 3. This refers to EPA acting once information compliant with a rule, etc., is submitted, whereas SLC required action only upon receipt of information that supports the (a)(3)(A) determination.

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8	period to prohibit or otherwise restrict the manufac-
9	ture, processing, distribution in commerce, use, or
10	disposal of the chemical substance, or manufacture
11	or processing of the chemical substance for a signifi-
12	cant new use, or any combination of such activities,
13	sufficient to allay the Administrator's initial concern
14	that, in the absence of sufficient information, the
15	substance or significant new use may present an un-
16	reasonable risk of injury to health or the environ-
17	ment

- 1 "(2) In selecting among prohibitions and other re-
- 2 strictions to include in an order to be issued by the Admin-
- 3 istrator to meet the standard under paragraph (1), the
- 4 Administrator shall consider, to the extent practicable
- 5 based on reasonably available information, costs and other
- 6 nonrisk factors.
- 7 "(3) If the Administrator issues an order under para-
- 8 graph (1), the submitter of the notice under subsection
- 9 (a) may commence manufacture of the chemical sub-
- 10 stance, or manufacture or processing of the chemical sub-
- 11 stance for a significant new use, pursuant to this sub-
- 12 section only in compliance with the restrictions specified
- 13 in the order.
- 14 "(4) Not later than 90 days after issuing an order
- 15 under paragraph (1), the Administrator shall consider
- 16 whether to promulgate a rule pursuant to subsection
- 17 (a)(2) that identifies as a significant new use any manu-
- 18 facturing, processing, use, distribution in commerce, or
- 19 disposal of the chemical substance that does not conform
- 20 to the restrictions imposed by the order, and, as applica-
- 21 ble, initiate such a rulemaking or publish a statement de-
- 22 scribing the reasons of the Administrator for not initiating
- 23 such a rulemaking.
- 24 "(5) An order may not be issued under paragraph
- 25 (1) respecting a chemical substance—

1	"(A) later than 45 days before the expiration of
2	the notification period applicable to the manufacture
3	or processing of such substance under subsection
4	(a), (b), or (c); and
5	"(B) unless the Administrator has, on or before
6	the issuance of the order, notified, in writing, each
7	manufacturer or processor, as the case may be, of
8	such substance of the determination which underlies
9	such order.";
10	(6) by amending subsection (f) to read as fol-
11	lows:
12	"(f) Protection Against Potential Unreason-
13	ABLE RISKS.—
14	"(1) Orders.—If the Administrator determines
15	that the manufacture, processing, distribution in
16	commerce, use, or disposal of a chemical substance
17	or a significant new use with respect to which notice
18	is required by subsection (a), or that any combina-
19	tion of such activities, may present an unreasonable
20	risk of injury to health or the environment in ac-
21	cordance with subsection $(a)(3)(A)$ —
22	"(A) the Administrator shall issue an
23	order, to take effect on or before the expiration
24	of the applicable review period to prohibit or
25	otherwise restrict the manufacture, processing,

	
1	distribution in commerce, use, or disposal of the
2	chemical substance, or of the chemical sub-
3	stance for a significant new use, sufficient to
4	allay the Administrator's initial concern that
5	the substance or significant new use may
6	present an unreasonable risk of injury to health
7	or the environment;
8	"(B) no person may commence manufac-
9	ture of the chemical substance, or manufacture
10	or processing of the chemical substance for a
11	significant new use, pursuant to this subsection
12	except in compliance with the restrictions speci-
13	fied in the order; and
14	"(C) not later than 90 days after issuing
15	an order under subparagraph (A), the Adminis-
16	trator shall consider whether to promulgate a
17	rule pursuant to subsection (a)(2) that identi-
18	fies as a significant new use any manufac-
19	turing, processing, use, distribution in com
20	merce, or disposal of the chemical substance
21	that does not conform to the restrictions im-
22	posed by the order, and, as applicable, initiate
23	such a rulemaking or publish a statement de-

scribing the reasons of the Administrator for

not initiating such a rulemaking.

24

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	12
1	"(2) Selecting prohibitions and restric-
2	TIONS.—In selecting among prohibitions and other
3	restrictions to include in an order to be issued by
4	the Administrator to meet the standard under para-
5	graph (1), the Administrator shall consider, to the
6	extent practicable based on reasonably available in-
7	formation, consider costs and other nonrisk factors, and
8	such an order shall include a requirement described in
9	section 6(a).
10	"(3) Persistent and bioaccumulative sub-
11	STANCES.—For a chemical substance that is subject
12	to the requirements of this subsection and that the
13	Administrator determines, with respect to persist-
14	ence and bioaccumulation, scores high for 1 and ei-

Commented [GB5]: Any requirement? Note this this doesn't limit EPA to imposing (a) requirements, it simply seems to require that the requirements we impose have to include a 6(a) requirement. Seems kind of arbitrary.

STANCES.—For a chemical substance that is subject to the requirements of this subsection and that the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), reduce the potential for exposure to the substance to the maximum extent practicable.

Commented [GB6]: Note deletion of "maximum" from required exposure reduction for PBTs.

"(4) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the

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1	Assistant Secretary of Labor for Occupational Safe-
2	ty and Health prior to adopting any prohibition or
3	other restriction under this subsection to address
4	workplace exposures.";
5	(7) by amending subsection (g) to read as fol-
6	lows:
7	"(g) Statement on Administrator Finding.—If
8	the Administrator finds, in accordance with subsection
9	(a)(3)(A), that a determination that the relevant chemical
10	substance or significant new use may present an unreason-
11	$able\ risk\ of\ injury\ to\ health\ or\ the\ environment\ is\ not\ warden above the support of\ the\ convergence of\ the\ convergence of\ the\ convergence of\ convergence of\ convergence of\ convergence\ converg$
12	ranted, then notwithstanding any remaining portion of the
13	applicable review period, the submitter of the notice may
14	commence manufacture for commercial purposes of the
15	chemical substance or manufacture or processing for a
16	commercial purposes for a significant new use, and the Ac
17	ministrator shall make public a statement of the Administrator shall make public a statement shall make public shall mak
18	trator's finding. Such a statement shall be submitted for
19	publication in the Federal Register as soon as is prac-
20	ticable before the expiration of such period. Publication
21	of such statement in accordance with the preceding sen-
22	tence is not a prerequisite to the manufacturing or proc-
23	essing of the substance with respect to which the state-
24	ment is to be published.";
25	(8) in subsection (h)—

Commented [GB7]: Why is this "a commercial purpose" but line 14 says "commercial purposes"? Actually, both should probably be dropped, since 5(i) defines manufacture and processing for purposes of the section to refer only to mfr and processing for commercial purposes.

1	(A) in paragraph $(1)(A)$, by inserting ",
2	including an unreasonable risk to a potentially
3	exposed or susceptible subpopulation identified
4	by the Administrator for the specific uses iden-
5	tified in the application" after "health or the
6	environment";
7	(B) in paragraph (2), by striking "data"
8	each place it appears and inserting "informa-
9	tion"; and
10	(C) in paragraph (4), by striking ". A rule
11	promulgated" and all that follows through "sec-
1	tion 6(c)" and inserting ", without consider-ation of costs or
2	other nonrisk factors, includ-
1	ing an unreasonable risk to a potentially ex-
2	posed or susceptible subpopulation identified by
12	the Administrator under the conditions of use $^{\prime\prime}$; and
13	(9) by amending subsection (i) to read as fol-
14	lows:
15	"(i) Definitions.—(1) For purposes of this section,
16	the terms 'manufacture' and 'process' mean manufac-
17	turing or processing for commercial purposes.
18	"(2) For purposes of this Act, the term 'requirement'
19	as used in this section shall not displace any statutory or
20	common law.
21	"(3) For purposes of this section, the term 'applicable

Commented [GB8]: The striking of this language changes the relationship between 5(a) and 5(h) in current TSCA. Under current TSCA, this exemption (5h4) applies the same standard as the standard of review under (a), the logic being that EPA can exempt from new chemical review chemicals that it can determine upfront will meet the applicable standard. Since the review standard under the amended section 5(a) would be without consideration of cost or other nonrisk factors, it's not clear why the standard to be excused from review would not include the same language about cost and nonrisk factors. (We had made a similar comment on SLC about the absence of the "cost and other nonrisk" language in (h)(1)(A), lines 1-6 at the top of this page).

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- 1 Administrator receives a notice under subsection (a)(1)
- 2 and ending on the date the Administrator makes a deter-
- 3 mination under subsection (a)(3)(A), as extended pursu-
- 4 ant to subsection (c) or (e)(1)(A).".

Commented [GB9]: This formulation seems to change (or at least confuses) the operation of the applicable review period from SLC. Under SLC, the period was a defined period of time: the 90 days given under (a), plus any extensions under b, c, or e. This HLC formulation appears to say that the period doesn't end until EPA makes the a3A determination. Note that neither this draft nor the SLC draft actually requires EPA ever to make the a3A determination (and this draft makes it seem even more discretionary, per the comment above). Maybe the intent is that the applicable period end following any extensions under c or e1A with or without a determination, but it doesn't really say that.

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From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 3/23/2016 6:57:37 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley)

[Adrian_Deveny@merkley.senate.gov]

Subject: Sen. Markey TSCA TA request - Section 14

Michal – got it – checking. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Wednesday, March 23, 2016 2:53 PM **To:** Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley)

<Adrian_Deveny@merkley.senate.gov>

Subject: TA request Section 14

Question - on the list in 14(b) of information generally protected from disclosure - are any of the items on the list items that EPA would currently not consider as CBI (unless it was publicly available etc)?

Thanks

Μ

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 3/2/2016 5:43:14 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall)

[Jonathan Black@tomudall.senate.gov]

Subject: RE: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal, we can do 3pm – ok? Can call Ex. 6 - Personal Privacy Code Ex. 6 - Personal Privacy Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Wednesday, March 02, 2016 12:28 PM **To:** Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall)

<Jonathan_Black@tomudall.senate.gov>

Subject: RE: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Adding Adrian and Jonathan

There is ZERO interest in preserving the problem you're describing below. We are attempting to eliminate that problem. We have text we did not have when I first sent the question in that I am pasting excerpts of below so you can understand what we are thinking about. We'd like to schedule a call with you guys this afternoon between 1:30-4:30 (perhaps with other folks as well) so we can resolve this. Does that work?

Michal

(4) RISK EVALUATION PROCESS AND DEADLINES.—

- (A) Not later than 1 year after enactment, the Administrator shall establish, by rule, a process to conduct risk evaluations in order to determine, without consideration of costs or other non-risk factors, whether a high-priority chemical substance presents an unreasonable risk of injury to health or the environment from exposure to the chemical substance under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant to the risk evaluation by the Administrator.
- (B) The Administrator shall conduct and publish a risk evaluation, in accordance with the rule promulgated under subparagraph (A), for a chemical substance—
 - (i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and
 - (ii) subject to subparagraph (D), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (A), be subjected to a risk evaluation.
- (C) The Administrator shall, as soon as practicable and not later than 6 months of each designation of a high priority substance, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible populations the Administrator expects to consider.
- "(E) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

- "(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible populations identified as relevant by the Administrator;
- "(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use was considered, and the basis for that consideration;
- "(iii) not consider information on cost and other factors not directly related to health or the environment;
- "(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and
- "(v) describe the weight of the scientific evidence for the identified hazard and exposure."

c) PROMULGATION OF SUBSECTION (a) RULES.

- (1) If, based on a risk evaluation conducted in accordance with the rule promulgated under subsection (b)(4)(A[MVL1]), the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, , the Administrator—
 - (A) shall propose a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey









From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Wednesday, March 02, 2016 12:09 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal,

This responds to your TA request on risk evaluations and unreasonable risk. Please let me know if any additional questions. Thanks,

Sven

Although there is too little detail to evaluate definitively, we have significant concerns with this proposed construct.

As you've described it, all risk management rules would still be subject to the current TSCA unreasonable risk standard, and EPA would still be limited by the same cost-benefit balancing analyses that have prevented effective action on chemicals in the past.

We also don't see the value in requiring EPA to issue a rule regarding risk evaluation with a preordained outcome: don't consider cost or other non-risk factors. This process will consume a significant amount of EPA time and resources, and delay the business of evaluating chemicals and protecting against identified risks. If Congress wants to preclude EPA from considering such factors in this context, the far more direct way to do so is by statutory directive.

Finally, if EPA is required to act by rule, commenters (and litigants) will likely argue that Congress must have intended EPA to have some discretion in the rulemaking, and will likely point to the authority to consider cost

as part of the risk management rulemaking to argue that EPA should be able to factor cost in some fashion into the underlying safety standard. As such, this proposed approach seems likely to leave unsettled for a protracted period of time the most significant TSCA policy shift made in both bills.

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Tuesday, March 01, 2016 4:53 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov > **Subject:** Section 6 - quick unreasonable risk q

Here is a construct being discussed:

- 1) epa promulgates a rule for how risk evaluations are supposed to be conducted study a chemical to decide whether it poses an unreasonable risk, and don't consider costs/non-risk factors the unreasonable risk "fix" is made in the rule itself.
- 2) later in the section, we tell people to conduct a risk evaluation in accordance with the rule above, in order to figure out whether the substance poses an unreasonable risk, but I do NOT remove cost consideration in this place because of the reference to the RULE, which does require the fix.

Any concerns with this description re "unreasonable risk"?

Thanks Michal

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/24/2016 12:10:09 AM

To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov; Adrian_Deveny@merkley.senate.gov

Subject: Sen. Markey TSCA TA on house section 14 (4-22)

Attachments: Markey.TSCA TA.House Section 14 (4-22).docx; ATT00001.htm

Michal,

The attached TA responds to the request on house section 14 (4-22).

Please note that we are making comments only on changes. This section, for example, still contains the troubling "mixed information" section that we commented on recently. We have not commented again on that, but it demonstrates why we want to be sure that this TA is not interpreted as comprehensive comments on these documents.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

RLSO comparison of HLC 4.18 to 4.22

[DISCUSSION DRAFT]

71_SEC. 1111. CONFIDENTIAL INFORMATION.		
82 Section 14 of the Toxic Substances Control Act (15		
Samul.S.C. 2613) is amended to read as follows:		
*SEC. 14. CONFIDENTIAL INFORMATION.		
"(a) In General.—Except as provided in this sec-		
+26tion, the Administrator shall not disclose information that		
is exempt from disclosure pursuant to subsection (a) of		
448 section 552 of title 5, United States Code, by reason of		
subsection (b)(4) of that section—		
4610 "(1) that is reported to, or otherwise obtained		
by, the Administrator under this Act; and		
# <u>12</u> "(2) for which the requirements of subsection		
19 <u>13</u> (c) are met.		
2014 In any proceeding under section $552(a)$ of title 5, United		
2415 States Code, to obtain information the disclosure of which		
has been denied because of the provisions of this sub-		
section, the Administrator may not rely on section		
2418_552(b)(3) of such title to sustain the Administrator's ac-		
25 <u>19</u> tion.		
(4)		
2620 "(b) Information Not Protected From Disclo-		

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 $30\underline{24}$ prohibit the disclosure of information that is not

othe relationship among these paragraphs is not en-	
tirehy clear į	Commented [GB1]: Agree – (b)(1) makes relationship confusing.
2822 "(1) Mixed confidential and noncon-	comusing.
2923 FIDENTIAL INFORMATION.—Subsection (a) does not	

1	protected from disclosure under this section on the
2	basis that such information contains information de-
3	scribed in subsection (a), subject to the condition
4	that the Administrator shall protect from disclosure
5	the information described in subsection (a) in dis-
6	closing the information that is not protected from
7	disclosure.
8	"(2)— ODATA: INFORMATION FROM—_HEALTH—AND—SAFETY
)	-studies.—øSubject-to-paragraph-(1).;-eubsection
109	Subsection (a) does not prohibit the disclosure of disc
10	closure of—
11	"(A) any health and safety study which is
12	submitted under this Act with respect to—
13	"(i) any chemical substance or mix-
14	ture which, on the date on which such
15	study is to be disclosed has been offered
16	for commercial distribution; or
17	"(ii) any chemical substance or mix-
18	ture for which testing is required under
19	section 4 or for which notification is re-
20	quired under section 5; and
21	"(B) any ødataginformation reported to, or otherwiseother
22	wise obtained by, the Administrator from a
i.	health

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23	and safety study which relates to a
	—chemical
24	substanceormixturedescribedin
2	—clause (i) or
2225	(ii) of subparagraph (A).

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[Discussion Draft]

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<u></u>	This paragraph does not authorize the prelease /_/
3	-disclosure?¿ of
2	_any posted which information, including formulas
3	(including molecular structures) of a chemical sub-
4	stance or mixture that discloses processes used in
43	-the
45	manufacturing or processing of a chemical substances wib
26	stance or mixture or, in the case of a mixture, the
5	leases of ødatas disclosing the portion of the mix-
7	turemixture comprised by any of the
3 <u>8</u>	chemical substances in the mixture.
6	the mixture, othis is copied exactly from existing
1	law should 'data' be updated to 'information' and
7	release-be-changed to-'disclosure-te-conformwith the
8	rest of the bill? z
49	"(3) Other information not protected
9	FROMDISCLOSURE.—&Subject_to_paragraph_(1), ¿
10	_subsection Subsection (a) does not probably)ro
5 <u>11</u>	<u>hibit</u> the disclosure of—
612	"(A) a risk evaluation published under sec-
7 <u>13</u>	tion 6: <u>(b):</u>
814	"(B) any general information describing
9 <u>15</u>	the manufacturing volumes, expressed as spe-
40 <u>16</u>	cific aggregated volumes or, if the Adminis-
1117	trator determines that disclosure of specific ag-
	(227222)

Commented [GB2]: One way or another, be consistent.

Commented [GB3]: This could be read to suggest that formulas always disclose process information and are therefore always withholdable. If that is not the intent, this could be revised as follows: "This paragraph does not authorize the [release][disclosure] of any information that discloses processes used in the manufacturing or processing of a chemical substance or mixture (including formulas (including molecular structures) that disclose such processes)..."

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42 <u>18</u> greg	gated volumes would reveal confidential in
4319 forn	nation, expressed in ranges; or

[Discussion Draft]

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1420	"(C) a general description of a process
<u> 4521</u>	used in the manufacture or processing and in-
16 <u>22</u>	dustrial, commercial, or consumer functions and
1723	uses of a chemical substance, mixture, or article
48 <u>24</u>	containing a chemical substance or mixture, in-
1925	cluding information specific to an industry or

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[Discussion Draft]

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1	industry sector that customarily would be
2	shared with the general public or within an in-
3	dustry or industry sector.
4	"(4) Bans and phase-outs.—
5	"(A) IN GENERAL.—If the Administrator
6	promulgates a rule pursuant to section 6(a)
7	that establishes a complete or partial ban or phase out with respect
ļ	to a condition of usephase out of a chemical substance or
8	mixture,
89	the protection from disclosure of any informa:
2	<u>informationtion</u> under this section with respect to
1()	the
911	chemical substance or mixture shall be pre-
1012	sumed to no longer apply, subject to subsection
H <u>13</u>	(g)(1)(E) and subparagraphs (B) and (C)() of
14	this paragraph.
12 15	"(B) Limitations.—
13.16	"(i) Critical use.—In the case of a
1417	chemical substance or mixture for which a
15 <u>18</u>	specific condition of use is subject to ##################################
3	exemption pursuant to section 6(1) every
4	teal use exemptions; need to check this ref

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[Discussion Draft]

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10	erence; g), if the
ļ	Administrator establishes a
20	ban or phase·
2	out described in subpara-
21	graphsubparagraph (A) with respect <u>re</u>
3	<u>-spect</u> to the chemical
23	_substance—_or—_mixture,—
4	-thepresumption
23	againstprotectionunder
\$	-suchsubpara-
24	graph subparagraph shall only apply to information in:
()	<u>formation</u> that
25	relates solely to any conditions condir

[Discussion Draft]

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7	<u>tions</u> of use of
1	the chemical substance or
\$	mixture <u>to</u> which
2	the exemption does not
+3	apply.
24	"(ii) Export.—In the case of a chem
35	ical substance or mixture for which there is
4 <u>6</u>	manufacture, processing, or distribution in
<u> 57</u>	commerce that meets the conditions of sec-
68	tion 12(a)(1), if the Administrator estab·
79	lishes a ban or phase out described in sub
<u>810</u>	paragraph (A) with respect to the chemical
911	substance or mixture, the presumption
1012	against protection under such subpara-
4413	graph shall only apply to information that
1214	relates solely to ##nyany other manufacture,
Q	processing, or distribution in commerce ¿
10	
13 <u>15</u>	tion-of-use-other-than-such-manufacture.
1	processing, or distribution in commerce??;
44 <u>16</u>	of the chemical substance or mixture, was unless

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[Discussion Draft]

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45 <u>17</u>	less the Administrator makes the determination
1618	mination in section 12(a)(2).
17 19	"(iii) Partial bans and phase-
1820	OUTS.—In the case of a chemical sub-
1921	stance or mixture for which the Adminis-
20 22	trator establishes a <u>partial</u> <u>ban or phase ent</u>
2123	seribedout described in subparagraph (A) with respective:
2224	spect to a specific condition of use of the chem-
2325	iealchemical substance or mixture, the presumptionpre

Commented [GB4]: This suggests that this clause addresses partial bans for specific uses – ie, the whole use is not banned. Presumably the intent is for the clause to address bans for specific uses (which are partial bans of the chemical). If that's the intent, suggest dropping "partial" here.

[Discussion Draft]

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1	sumption against protection under such
2	graphsubparagraph shall only apply to informationinforma:
	<u>tion</u> that
3	relates solely to the condition of
2	use of the
4	chemical substance or mixture
2	for which
5	the ban or phase out is established established.
26	lished.
37	"(C) Request for nondisclosure.—
4 <u>8</u>	"(i) In GENERAL.—A manufacturer
<u>\$9</u>	or processor of a chemical substance or
610	mixture subject to a ban or phase out de-
711	scribed in this paragraph may submit to
812	the Administrator, within 30 days of re-
913	ceiving a notification under subsection
40 <u>14</u>	(g)(2)(A), a request, including documenta-
<u>++15</u>	tion supporting such request, that some or
42 <u>16</u>	all of the information to which the notice
1317	applies should not be disclosed or that its

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[Discussion Draft]

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1418	disclosure should be delayed, and the Ad-
XYX O	and the real
<u> 1519</u>	ministrator shall review the request under
46 <u>20</u>	$_{\rm subsection}$ (g)(1)(E).
17 21	"(ii) Effect of no request or de-
1822	_NIAL.—If no request for nondisclosure or
1923	_delay is submitted to the Administrator
2024	_under this subparagraph, or the Adminis
2125	_trator denies such a request under sub-

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[Discussion Draft]

7

	ı
ļ	section (g)(1)(A), the Administrator shall
1	promptly make the information public shall not
2	be protected from disclosure under this
3	section
24	"(5) CERTAIN REQUESTS.—If a request is made
35	to the Administrator under section 552(a) of title 5,
46	United States Code, for information **reported reported to or
<u>57</u>	otherwise obtained by the Administrator under this
2	fAct/nlle $pprox 2 Act$ that is not protected from disclosure
8	under this
3	subsection, the Administrator may not
9	deny the requestre:
4	<u>quest</u> on the basis of section 552(b)(4)
10	of title 5,
611	United States Code.
712	(c) Requirements for Confidentiality
8 <u>13</u> C	LAIMS.—
9 <u>14</u>	"(1) Assertion of claims.—
4015	"(A) IN GENERAL.—A person seeking to
<u> 4416</u>	protect from disclosure any information that
12<u>17</u>	person submits under this @Act + title 2
<u>.</u> š	aluding_information <u>mation</u> described in paragraph (2))

Commented [SD5]: Change from Senate version. Would make information nonconfidential without requiring that EPA make it public immediatelty.

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[Discussion Draft]

8

18	_shall assert
	to the Administrator a claim for
19	protection
2	-from disclosure concurrent with sub-
20	_mission <u>submission</u> of
3	the information, in accordance with
21	_such rules
4	-regarding a claim for protection from
22	disclosure
Ş	as the Administrator has promul-
23	gated promulgated or—_may-
1324	_promulgate_pursuant—_to—_this_ <u>title</u>
6	-ølitle:

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[Discussion Draft]

8

1	"(B) Inclusion.—An assertion of a claim
2	under subparagraph (A) shall include a state
3	ment that the person has—
4	"(i) taken reasonable measures to pro-
5	tect the confidentiality of the information;
6	"(ii) determined that the information
7	is not required to be disclosed or otherwise
8	made available to the public under any
9	other Federal law;
10	"(iii) a reasonable basis to conclude
11	that disclosure of the information is likely
12	to cause substantial harm to the competi-
13	tive position of the person; and
14	"(iv) a reasonable basis to believe that
15	the information is not readily discoverable
16	through reverse engineering.
17	"(C) Additional requirements for
18	CLAIMS REGARDING CHEMICAL IDENTITY IN-

[Discussion Draft] 96

19	FORMATION.—In the case of a claim under sub-
20	paragraph (A) for protection from disclosure of
21	a specific chemical identity, the claim shall in-
22	clude a structurally descriptive generic name for
23	the chemical substance that the Administrator
24	may disclose to the public, subject to the condi-
25	tion that such generic name shall—

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	97
1	"(i)— <u>be</u> consistent—with—guidance <u>+devel-</u>
<u> </u>	\$sec_questions_below_regarding_guidance;
2	issuedoped by the Administrator under para-
3	graph (4)(A); and
4	"(ii) describe the chemical structure
5	of the chemical substance as specifically as
6	practicable while protecting those features
7	of the chemical structure—
8	"(I) that are claimed as confiden·
9	tial; and
10	"(II) the disclosure of which
11	would be likely to cause substantial
12	harm to the competitive position of
13	the person.
14	"(2) Information generally not subject
15 то	SUBSTANTIATION REQUIREMENTS.—The fol-
	ing information <i>s, as identified by the</i> <i>imis</i> information shall not be subject to substan
<u> </u>	or,72 Othis would clarify that the Administrator

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[Discussion Draft]

97

<u>}</u>	
<u> 2</u>	—— something falls into one of these eategories, as dis-
3	cussed;-shall-not-be-subject-to-substantiation-re-
17	quirements tiation requirements under paragraph (3)
18	"(A) Specific information describing the
19	processes used in manufacture or processing of
20	a chemical substance, mixture, or article.
21	"(B) Marketing and sales information.
22	"(C) Information identifying a supplier or
23	customer.

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[Discussion Draft]

10

1	"(D) In the case of a mixture, details of
2	the full composition of the mixture and the $\operatorname{re}^{\boldsymbol{\cdot}}$
3	spective percentages of constituents.
4	"(E) Specific information regarding the
5	use, function, or application of a chemical sub-
6	stance or mixture in a process, mixture, or arti-
7	cle.
8	"(F) Specific production or import volumes
9	of the manufacturer <u>or processor</u> .
10	"(G) Prior to the date on which a chemical
11	substance is first offered for commercial dis-
12	tribution, the specific <u>chemical</u> identity of the chemical
13	chemical_substance,~_includingthechemical
4	name, melec-
14	włarmolecular formula, Chemical Abstracts
<u> </u>	Service-num:
15	ber <u>number</u> and other information that
6	would identify

Commented [GB6]: This is harmless but adds nothing, because anyone producing or importing a chemical will be a manufacturer.

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[Discussion Draft]

98

16	the specific chemical substance,
	if the specific
17	<u>chemical</u> identity was claimed as
2	confidential at the time
18	it was submitted in a
<u> 13 19 </u>	notice under section 5.
<u> 1420 </u>	"(3) Substantiation requirements.—Ex-
15 <u>21</u>	cept for information described in paragraph (2), a
46 <u>22</u>	person asserting a claim to protect information from
47 <u>23</u>	disclosure under this section **hallshall substantiate the
24	claim, in accordance with <u>such rules as the Adminis</u> -

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[Discussion Draft]

11

1	trator has promulgated, and or may promulgate pursuant
<u> </u>	-consistent with guidance developed,; øthis seems
4	
<u>"</u> Ž	torily-required to follow the guidencett-would-prob-
6	ably end up being treated the same as a rule from a
7	procedural-standpoint,-so-to-the-extent-that-letting-the
<u> </u>	-Administrator-do-some-things-through-guidance-in-
9	stead of a rule is intended to obviate the need for full
1 0	rulemaking-procedures, this might-negate-that-if-that
11	is a problem, might be better to say something more
12	-general-here, like-shall-substantiate-the-claim-in-ac-
13	-cordance with such-requirements as the Administrator
2	may ostablish 2 by the Administratorsection.
3	"(4) GUIDANCE.—The Administrator shall de-
14	velop@guidance; @so, just checking, is this intended
<u> 15</u>	to be true guidance, or is it meant to be required to
16	

sound like they are requirements; regarding—

Commented [GB7]: This has been changed so that the substantiation guidance EPA develops under paragraph (4) is no longer binding – substantiation must be in accordance with any EPA rules, but not consistent with guidance.

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[Discussion Draft]

99

5	"(A) the determination of structurally de-
6	scriptive generic names, in the case of claims
7	for the protection from disclosure of specific
8	chemical identity; and
9	"(B) the content and form of the state
10	ments of need and agreements required under
11	paragraphs (4), (5), and (6) of subsection (d).
12	"(5) CERTIFICATION.—An authorized official of
13	a person described in paragraph (1)(A) shall certify
14	that the statement required to assert a claim sub-
15	mitted pursuant to paragraph (1)(B), and any infor-
16	mation required to substantiate a claim submitted
17	pursuant to paragraph (3), are true and correct.
18	"(d) Exceptions to Protection From Disclo-
19	SURE.—Information described in subsection (a)—
20	"(1) shall be disclosed to an officer or employee
21	$of the United States -\!\!\!\!-$
22	"(A) in connection with the official duties
23	of that person under any <u>Federal</u> law for the protection
24	protection of health or the environment; or

F:\KML\114\EC\TSCA\SEC14_02.XML [Discussion Draft] 12 1 "(B) for a specific Federal law enforcement pure nforce. 2 perement purpose; 3 "(2) shall be disclosed to a contractor of the Commented [GB8]: These change explicitly limit the disclosure to federal employees to the situation where it's required to carry out Federal law, but that was probably implied anyway.

United States and employees of that contractor-

4

7

12

13

8 tract with the United States for the perform-

9 ance of work in connection with this Act; and

10 "(B) subject to such conditions as the Ad-

11 ministrator may specify;

"(3) shall be disclosed if the Administrator de

termines, without consideration of costs or otherthat disclosure is necessary to protect

factory performance by the contractor of a con-

-non-risk factors, that disclosure is necessary to pro-

teet health or the environment against an unreasons unreasonable

15 able-risk of injury to health or the environment, without

4516 consideration of costs or other nonrisk factors in.

46<u>17</u> cluding an unreasonable risk to a potentially exposed

or susceptible subpopulation identified as relevant by

#819 the Administrator under the conditions of use;

4920 ______"(4) shall be disclosed to a State, political sub-

division of a State, or tribal government, on written

2122 request, for the purpose of administration or en-

forcement of a law, if such entity has 1 or more ap-

2324 plicable agreements with the Administrator that are

2425 consistent with the *guidance guidance developed under sub.

Commented [GB9]: Need to drop this comma

Commented [GB10]: Move seems ok but be consistent — it appears after "determines" in other formulations in the bill (or at least it did — maybe those have all been changed).

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13

- 1 section (c)(4)(B) and ensure that the entity will take
- 2 appropriate measures, and has adequate authority,
- 3 to maintain the confidentiality of the information in
- 4 accordance with procedures comparable to the proce-

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[Discussion Draft]

101

5	dures used by the Administrator to safeguard the in-
6	formation;
7	"(5) shall be disclosed to a health or environ
8	mental professional employed by a Federal or State
9	agency or tribal government or a treating physician
10	or nurse in a nonemergency situation if such person
11	provides a written statement of need and agrees to
12	sign a written confidentiality agreement with the Ad-
13	ministrator, subject to the conditions that—
14	"(A) the statement of need and confiden-
15	tiality agreement are consistent with the pguidguid-
16	ance developed under subsection (c)(4)(B);
17	"(B) the statement of need shall be a
18	statement that the person has a reasonable
19	basis to suspect that—
20	"(i) the information is necessary for,
21	or will assist in—
22	"(I) the diagnosis or treatment of
23	1 or more individuals; or
24	"(II) responding to an environ-
25	mental release or exposure; and

Commented [GB11]: Note that this guidance remains "enforceable", whereas the substantiation guidance now is not.

[Discussion Draft] 14

1	"(ii) 1 or more individuals being diag
2	nosed or treated have been exposed to the
3	chemical substance or mixture concerned,
4	or an environmental release of or exposure

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	102
5	to the chemical substance or mixture con-
6	cerned has occurred; and
7	"(C) the person will not use the informa-
8	tion for any purpose other than the health or
9	environmental needs asserted in the statement
10	of need, except as otherwise may be authorized
11	by the terms of the agreement or by the person
12	who has a claim under this section with respect
13	to the information, $\phi \underline{\bullet} \underline{\bullet} \underline{\bullet} \underline{\bullet} \underline{\bullet} \underline{\bullet} \underline{\bullet} \underline{\bullet}$
14	title prohibits the disclosure of any such infor-
15	mation through discovery, subpoena, other
16	court order, or any other judicial process other
17	$wise \ allowed \ under \ applicable \ Federal \ or \ State$
2	
3	
<u>18</u>	law)
48 <u>19</u>	"(6) shall be disclosed in the event of an emer-
<u>20g</u> e	ency, to a treating <u>or responding</u> physician, nurse,
4aş	gent of a polic
	<u>mpoison</u> control center, public health or nvironmentalen:
22 vi	ronmental official of a State, political subdivision
<u></u> of	a State, or
<u>23t</u>	ribal government, or first responder
6———(i: f:\VHLC\041816\041816.252.xml April 18, 2016 (3:08 p.m.)	ncluding any (627896 8)

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24 individual duly authorized by a Federal Federal

7 eral agency,

25 State, political subdivision of a State, or

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[Discussion Draft]

103

3	earlice officer, firefighter, or emergency medical techniciantechnic
<u> </u>	<u>cian</u>) if
4	such person requests the information, subjectsub:
2	— <u>jeci</u> to the
35	conditions that such person shall—
46	"(A) have a reasonable basis to suspect
57	that—
<u>48</u>	"(i) a medical, public health, or envi-
79	ronmental emergency exists;
\$ <u>10</u>	"(ii) the information is necessary for,
911	or will assist in, emergency or first aid di-
10 <u>12</u>	agnosis or treatment; or
<u> 4413 </u>	"(iii) 1 or more individuals being di-
12 <u>14</u>	agnosed or treated have likely been ex-
43 <u>15</u>	posed to the chemical substance or mixture
44 <u>16</u>	concerned, or a serious environmental re-
45 <u>17</u>	lease of or exposure to the chemical sub-
46 <u>18</u>	stance or mixture concerned has occurred;
<u>19</u>	and
47 <u>20</u>	"(B) if requested by a person who has a
<u> 1821 </u>	claim with respect to the information under this
	section—
20 <u>23</u>	"(i) provide a written statement of
2124	need and agree to sign a confidentiality

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104

3such	
34statementofneedandconfidentiality	
45 agreement as soon as practicable, but not	
\$6necessarily before the information is dis-	
6 <u>7closed;</u>	
78(7) may be disclosed if the Administrator de-	
89termines that disclosure is relevant in a proceeding	
910 under this Act, subject to the condition that the dis-	
doll closure is made in such a manner as to preserve con-	
1112fidentiality to the *maximum* extent practicable without impair:	<u>t</u>
1213 without impairinging the proceeding; sor/and;	
"(8) shall be disclosed if the information is re-	
quired to be disclosed or otherwise made public	
15 under any other provision	
14 <u>16</u> of Federal law.	
4517 "(e) Duration of Protection From Disclo-	
2 "(1) In general.—Subject to paragraph (2),	
19 the The Administrator shall	
protect from disclosure	
20 formation information described in subsectionsub-	
17 <u>21 section (a)</u> —	Commented [SD12]: Language does not reflect
4822 "(A) in the case of information described	suggested changes from the Senate.
in subsection (c)(2), until such time as—	

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$F:\KML\114\EC\TSCA\2016_02.XML$	[Discussion Draft]
2024	104 "(i) the person that asserted the claim
2125	notifies the Administrator that the person

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[Discussion Draft]

17

 $1 \hspace{1.5cm} \text{is withdrawing the claim, in which case the} \\$

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[Discussion Draft]

18

5\041816.252.xml 3:08.p.m.)	information <u>infor</u> (627896)8	the other citations – we don't see how they are needed.
14	vent conflicting deadlines; in the case of	 Commented [GB14]: "Subject to paragraph (2) was stricken in (A) and should be stricken here, along with
13	(f)(3), and section 8(b), a plink is needed to pre-	
12	"(B) øsubject to paragraph (2), subsection	
11	<u>(g); and</u>	
10		
9	no, how does a roview there interact with	
ф	information strike?; (2) and decides it no longer qualifies? If	 Commented [GB13]: (f) does apply to c2 information
***************************************	under (f)? (f) appears to not apply to (c)(2)	Commented ICP121: (f) dead and the artists and
10	subsection(s (f) and; (what would happen	
5 <u>8</u> 9		
	take any actions required under sub- section (b) and schould this instead be that	
7	shall	
<u> </u>	first? <u>Stion</u> in which case the Administrator	
4	through the review process in paragraph (2)	
	- 20 300	
46	this section; \$\psi \cdot \cdo	
	protection from disclosure under	
5	ifyqualify for	
4 2	becomes aware that the information does not qual-	
	"(ii)—_the—Administrator—shecomes	
3	formation available to the public disclosure under this section; or	
2	Administrator information shall promptly make the in-not be protected from	

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11	18 —— <u>mation</u> other than	
613	information described in subsection (e)(2) sub-	
16	section (c)(2)	
7 <u>17</u>	"(i) for a period of 10 years <i>of rom</i> from the	
12	date on which	
<u>818</u>	<u>"(1) who the</u> person submits asserts the <i>in</i> claim	
19	formation with respect to the Administrator information to the Ad-	Commented [SD15]: should be "submitted to the Administrator".
9 <u>20</u>	ministrator; or;	
13	"(11) Øiko Administrator makes-a	
14	determination that the claim-continues	
15	to-meet the relevant requirements of	
16		

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	105
<u> </u>	reassort-and-substantiane-ar-resubstan-
<u> </u>	tiate a claim under paragraph (2) ¿- ox
4021	"(ii) woif applicable before the september
	<u>expira-</u>
11 22	tion of such 10-year period or any extension, i osince
	<u>Uus is</u>
<u>23</u>	pransed under subparagraph (B), <u>an 'Or' list and (i)</u>
	<u>Ins a set period, need a</u>
1224	Title to decide which clause applies: until

#325 such time as—

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	19
1	"(I) the person that asserted the
2	claim notifies the Administrator that
3	the person is withdrawing the claim,
4	in which case the Administratorinformation shall
3	premptly make the information avail-
<u> </u>	able to the publicated be protected from disclosure
5 <u>6</u>	under this section; or
67	"(II) the Administrator
78	aware that the information does not
<u>89</u>	qualify for protection from disclosure
910	under this section in which case the
10 11	Administrator shall take any actions
12	required under subsectionsubsections (f)
13	(g) <i>@#\$</i>
4	above-regarding-interaction-with-para-
3	
14	"(2) Extensions.—
15	"(A) IN GENERAL.—In the case of infor-
16	mation other than information described in sub-
17	section (c)(2), not later than the date that is 60
18	days before the expiration of the period de-

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Commented [SD17]: change in Senate version. Means that EPA would not necessarily have to immediately make the information public.

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[Discussion Draft]

106

19	scribed in paragraph (1)(B <u>)(i</u>), the Administrator <u>Adminis</u> :
20	<u>irator</u> shall provide to the person that asserted
ļ	-the
21	claim a notice of the impending expiration
2	of
2022	the period.
2123	"(B) Request.—
2224	"(i) IN GENERAL.—Not later than the
2325	date that is 30 days before the expiration

[Discussion Draft]

20

1	of the period described in paragraph
2	(1)(B)(i), a person reasserting the relevant
3	claim shall submit to the Administrator a
4	request for extension substantiating, in ac-
5	cordance with subsection (c)(3), the need
6	to extend the period.
7	"(ii) Action by administrator.—
8	Not later than the date of expiration of the
9	period described in paragraph (1)(B;, the)(i).
10	the Administrator—shall, in—accordance—with
11	subsection(g)(1)—
12	"(I) review the request submitted
13	under clause (i);
14	"(II) make a determination re-
15	garding whether the claim for which
16	the request was submitted continues
17	to meet the relevant requirements of
18	this section; and

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	107
19	"(III)(aa) grant an extension of
20	10 years; or
21	"(bb) deny the request.
22	"(C) No limit on number of exten-
23	SIONS.—There shall be no limit on the number
24	of extensions granted under this paragraph, if

1	the Administrator determines that the relevant
2	request under subparagraph (B)(i)—
3	"(i) establishes the need to extend the
4	period; and
5	"(ii) meets the requirements estab
6	lished by the Administrator.
7	"(f) REVIEW AND RESUBSTANTIATION.—
	øis anything in this subsection intended to apply to
02) information? ¿
8	"(1) Discretion of administrator.—The
3	-Administratormay-requires, under this subsection,
3	- Www. docs this add/ alary to require strike? t- any person
9	thathas
910	claimed protection for information from dis-disclosure
3	— vlosure under this section, whether before, on, or
11	after the
10 <u>12</u>	_date of enactment of the Frank R. Lauten- <u>Lautenberg</u>
4413	berg-Chemical Safety for the 21st Century Act, to re-
1214	reassertassert and substantiate or resubstantiate the claim
<u> 13 15</u>	_in accordance with subsection@subsection (c)_) / this section?;
16	øsee below:
14 <u>17</u>	"(A) after the chemical substance is sites des
15 <u>18</u>	ignated as a high-priority substance under sec-
46 <u>19</u>	tion 6(b); preed to check this reference;);
16\041816.252. (3:08 p.m.)	xml (627896 8)

Commented [GB18]: It applies equally to (c)(2) information and non-(c)(2) information. What about the text would suggest otherwise?

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[Discussion Draft]

22

1	"(C) if the Administrator determines that
2	disclosure of certain information currently pro-
3	tected from disclosure would be important to
4	assist the Administrator in conducting risk
5	evaluations or promulgating rules under section
106	6.
7	"(2) REVIEW REQUIRED.—The Administrator
8	shall review a claim for protection of information
9	from disclosure under this section and require any
10	person that has claimed protection for that informa-
11	tion, whether before, on, or after the date of enact-
12	ment of the Frank R. Lautenberg Chemical Safety
13	for the 21st Century Act, to reassert and substan-
14	tiate or resubstantiate the claim in accordance with
15	us <u>øthis</u> section—/subsection (c)?z øsec abovez—
16	"(A) as necessary to determine whether
17	the information qualifies for an exemption from
18	disclosure in connection with a request for in-
19	formation received by the Administrator under

section 552 of title 5, United States Code;

Commented [GB19]: Agree that these two provisions should be consistent. "This section" may be better.

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20

F:\KML\114\EC\TSCA\2016_02.XML [Discussion Draft] 109 21 "(B) if the Administrator has a reasonable 22 basis to believe that the information does not 23 qualify for protection from disclosure under this 24 section; or

[Discussion Draft]

110

1	"(C) for any chemical substance the Ad-
2	ministrator determines ingin accordance with see-
ļ	tion &Gunder(; section 5(b)(4)(A) & &need to check this reference &
3	presents_an—wreasonable—_unrear
2	<u>sonable_risk_ofinjuryto</u>
34	health or the environment environ:
	øment.
4 <u>6</u>	"(3) PERIOD OF PROTECTION.—If the AdminAdminis
\$ <u>7</u>	<u>istratortrator</u> requires a person to reassert and substan- substantiate
3	tiate or resubstantiate a claim under this paragraph,
8	subsection, and
69	determines that the claim continues to meet the <u>rel</u> -
710	<u>relevanteeant</u> requirements of this section, the Administrator
4	shall protect the information subject to the
11	claim
3	from disclosure for a period of 10 years from
12	the
<u> 813</u>	date of such determination, subject to any subse-
914	quent requirement by the Administrator under this
6	paragraph. *depending on answers in (1)(4). this
7	may be entirely taken care of there, if so, strike this
8	subpavagrapis-į-į
15	subsection.

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111

1016 "(g) DUTIES OF ADMINISTRATOR.—

1117 "(1) DETERMINATION.—

1218 "(A) IN GENERAL.—Except for claims re
1319 garding information described in subsection

[Discussion Draft]

110

1420	(c)(2), the Administrator shall, subject to sub
<u> 1521</u>	paragraph (C), not later than 90 days after the
46 <u>22</u>	receipt of a claim under subsection (c), and not
1723	later than 30 days after the receipt of a request
18 <u>24</u>	for extension of a claim under subsection (e) or
1925	a request under subsection (b)(4)(\(\subseteq\)(), review

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1	and approve, approve in part and deny in part,
2	or deny the claim or request. <i>Ogiven what's in</i>
į	(C) and (D), what does this subparagraph-aon
2	ally-do?÷
3	"(B) Reasons for Denial.—If the Ad-
4	ministrator denies or denies in part a claim or
5	request under subparagraph (A) the Adminis-
6	trator shall provide to the person that asserted
7	the claim or submitted the request a written
8	statement of the reasons for the denial or de-
9	nial in part of the claim or request.
10	"(C) Subsets.—The Administrator
11	shall—
12	"(i) except for elaims with respect to information
<u> </u>	described—_in
13	subsection (c)(2)(G), review
4	all claims or
14	requests under this section for
Ş	——————————————————————————————————————
15	tienprotection from disclosure of the specific
6	<u>cific chemical identity</u>
16	of a chemical substancesub:
1217	stance; and

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[Discussion Draft]

111

1318	"(ii) review a representative subset,
<u> 1419</u>	comprising at least 25 percent, of all other
43 <u>20</u>	claims or requests for protection from dis-
4621	closure under this section.
1722	"(D) EFFECT OF FAILURE TO ACT.—The
1823	failure of the Administrator to make a decision
49 <u>24</u>	regarding a claim or request for protection from
2025	disclosure or extension under this section shall

[Discussion Draft]

25

1	not have the effect of denying or eliminating a
2	claim or request for protection from disclosure.
3	"(E) Determination of requests
4	UNDER SUBSECTION (b)(4)(C).—With respect to
5	a request submitted under subsection (b)(4)(C),
6	the Administrator shall, with the objective of
7	ensuring that information relevant to the pro-
8	tection of health and the environment is dis-
9	closed_to_the- ømaximum; extent practicable, <u>determine</u>
1	determine whether the documentation provided
10	by the personper
2	<u>son</u> rebuts what shall be the pre-
11	sumption presumption of the
3	Administrator that the public
12	interest in the
4	disclosureoftheinformation-out-
13	weighsthe
<u> 5</u>	public or proprietary interest in
14	maintaining the
6	protection for all or a portion
15	of the information informa
7	<u>tion</u> that the person has re-

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[Discussion Draft]

112

16	quested <u>requested</u> not be disclosed <u>dis:</u>
	<u>losed</u> or for which disclosure
40 <u>17</u>	be delayed.
4418	"(2) Notification.—
12 <u>19</u>	"(A) IN GENERAL.—Except as provided in
43 <u>20</u>	subparagraph (B) and subsections (b), (d), and
<u> 1421 </u>	(e), if the Administrator denies or denies in
15 22	part a claim or request under paragraph (1),
4623	concludes, in accordance with this section, that
1724	the information does not qualify <code>@or-no-longorfor</code> <pre>protection</pre>
2	qualifies; <i>predundant, okay to strike?;</i> for pro-
<u> 1825 </u>	tection-from disclosure, intends to disclose in- information

formation

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[Discussion Draft]

26

3	—pursuant to subsection (d), or pro-
<u> </u>	<u>mulgatespromulgates</u> a
4	rule under section 6(a) establishing
2	a ban or
5	phase out with respect to a chemical
3	substance
6	—or mixture, the Administrator shall
4	notify, in
<i>7</i>	writing, the person that asserted the
5	claim or
<u> Ş</u>	submitted the request of the intent of
<u> </u>	the Administrator <u>Ad·</u>
17	ministrator to disclose the information, or not
8	protect the information from disclosure under
9	this section. The notice shall be furnished by
9	certified mail
10	(return receipt requested), by personalper
40	<u>sonal</u> delivery,
211	or by any other / any e means that allows
312	verification of the fact and date of receipt.
413	"(B) Disclosure of Information.—Ex-
	cept as provided in subparagraph (C), the Ad-
615	ministrator shall not disclose information under

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[Discussion Draft]

113

716	this subsection until the date that is 30 days
8 <u>17</u>	after the date on which the person that asserted
9 <u>18</u>	the claim or submitted the request receives noti-
4019	fication under subparagraph (A).
4420	"(C) Exceptions.—
1221	"(i) Fifteen day notification.—
<u> 1322</u>	For information the Administrator intends
14 <u>23</u>	to disclose under subsections (d)(3), (d)(4),
15 24	(d)(5), and (ii), the Administrator shall not
46 <u>25</u>	disclose the information until the date that

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1	is 15 days after the date on which the per-
2	son that asserted the claim or submitted
3	the request receives notification under sub-
4	paragraph (A), except that, with respect to
5	information to be disclosed under sub-
6	section———(d)(3),——— <u>if</u> the Administrator——deter
7	minesthatdisclosureoftheinformationis
8	necessary to protect against an imminent
9	and substantial harm to health or the envi-
10	ronment, in which case no prior notification shall be nec-
1	-tim-shall-be-newseany-
:	essary.
1112	"(ii) Notification as soon as prac-
1213	TICABLE.—For information the Adminis
13 14	_trator intends to disclose under paragraph
1415	(6) of subsection (ed), the Administrator

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[Discussion Draft]

114

15 16	shall notify the person that submitted the
4617	information that the information has been
47 <u>18</u>	disclosed as soon as practicable after dis-
18 19	closure of the information.
1920	"(iii) No notification required.—
2021	Notification shall not be required—
2122	"(I) for the disclosure of infor-
2223	
	or (8) of subsection (d); or

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F:\KML\114\EC\TSCA\SEC14 02.XML [Discussion Draft] 28 "(II) for the disclosure of infor-1 2 mation for which-"(aa) the Administrator has 3 provided to the person that as-5 serted the claim a notice under subsection (e)(2)(A); and 6 "(bb) such person does not 7 8 submit to the Administrator are-9 quest under subsection (e)(2)(B) 10 on or before the deadline estab. lished in subsection (e)(2)(B)(i). 11 "(D) Appeals.— 12 "(i) ACTION TO RESTRAIN DISCLO-13 SURE.—If a person receives a notification 14 under this paragraph and believes the in-15 16 formation is protected from disclosure

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115

17	under this section, before the date or
18	which the information is to be disclosed
19	pursuant to subparagraph (B) or (C); th
20	person may bring an action to restrain dis-
21	closure of the information in—
22	"(I) the United States district
23	court of the district in which the com-
24	plainant resides or has the principal
25	place of business; or

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	29
1	"(II) the United States District
2	Court for the District of Columbia.
3	"(ii) No disclosure.—
4	"(I) IN GENERAL.—The Admin
5	istrator shall not disclose any information
<u> </u>	mation that is the subject of an ap-
6	<u>peelappeal</u> under
2	thisparagraphbeforethe
7	dateon
3	which the applicable court
8	rules on an
69	action under clause (i).
710	"(II) Exception.—Subclause (I)
811	shall not apply to disclosure of infor-
9 <u>12</u>	mation described under subsections
22 <u>13</u>	(d)(4) and (ij).
14	"(3) Request and notification system.—
15	The Administrator, in consultation with the Director
16	of the Centers for Disease Control and Prevention,

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116

17	shall develop a request and notification system that,
18	in a format and language that is readily accessible
19	and understandable, allows for expedient and swift
20	access to information disclosed pursuant to para-
21	graphs (5) and (6) of subsection (d).
22	"(4) Unique identifier.—The Administrator
23	shall—
24	"(A)(i) develop a system to assign a
25	unique identifier to each specific chemical iden-

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[Discussion Draft]

116

1	tity for which the Administrator approves a re-
2	quest for protection from disclosure, which shall
3	not be either the specific chemical identity or a
4	structurally descriptive generic term; and
5	"(ii) apply that identifier consistently to all
6	information relevant to the applicable chemical
7	substance;
8	"(B) annually publish and update a list of
9	chemical substances, referred to by their unique iden-
10	tifieridentifiers, for which claims to protect the specificspe
11	<u>cific</u> chemical identity from disclosure have been-ap-
12	provedapproved, including the expiration date for each
13	such claim;
14	"(C) ensure that any nonconfidential infor-
15	mation received by the Administrator with re-
16	spect to a chemical substance included on the

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117

17	list published under subparagraph (B) while the
18	specific chemical identity of the chemical sub-
19	stance is protected from disclosure under this
	section
2	(i) øis made public; and z øthis seems
3	to-contradior-the-policy-described-in-the
4	meeting-thus not-all-nonconfidential-infor-
<u> Ş</u>	mation needs to affirmatively be made pub-
6	lie_how_does_this_subparagraph_fit_in_to
7	that-policy?-z
Ş	identifies the chemical substance
20	using
2021	the unique identifier; and
2122	"(D) for each claim for protection of a spe-
2223	cific chemical identity that has been denied by
2324	the Administrator or expired, or that has been
2425	withdrawn by the person who asserted the

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31

1		claim, and for which the Administrator has
2		used a unique identifier assigned under this
3		paragraph to identify protect the specific chemical iden:
4		tity in information that the Administrator has
5		made public, clearly link the specific chemical
6		identity to the unique identifier in such infor-
7		mation to the maximum extent practicable.
8	"(h)	CRIMINAL PENALTY FOR WRONGFUL DISCLO-
9	SURE.—	

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118

10	"(1) Individuals subject to penalty.—
11	"(A) IN GENERAL.—Subject to subpara-
12	graph (C) and paragraph (2), an individual de-
<u> </u>	scribedinsubparagraph(B)shallbe
2	—a-misdemeaner and e-øJudiciary drafters suggest
13	that this is unnecessary, strike?; fined
<u> 3</u>	under
13 <u>14</u>	title 18, United States Code, or imprisoned forimpris:
1 4 <u>15</u>	oned for not more than 1 year, or both.
45 <u>16</u>	"(B) DESCRIPTION.—An individual re-
46 <u>17</u>	ferred to in subparagraph (A) is an individual
47 <u>18</u>	who—
18 19	"(i) pursuant to this section, obtained
4920	possession of, or has access to, information
2021	protected from disclosure under this sec-
2122	tion; and
2223	"(ii) knowing that the information is
	protected from disclosure under this sec-
4	tion, willfully to dudiciony drafture note
<u> </u>	that this could be interpreted in this context
6	
7	tionally', if there is a preferred policy, bet
8	
	wise can leave up to the courts twillfully discloses
25	the information in
<i>≦</i>	(62789618)

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40 any manner to any per-

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1	senperson not entitled to
ļ	receive that informa-
1 <u>2</u>	tioninformation.
23	"(C) Exception.—This paragraph shall
34	not apply to any medical professional (including
45	an emergency medical technician or other first
\$ <u>6</u>	responder) who discloses any information 🍪 📆
67	tained under paragraph (5) or (6) of subsection
2	(d);)to@the-affected-patient/apatienttreated
78	by the medical <i>professional; \$, or the legal</i> reparefes
9	resentativesional, or to a person authorized to make med:
810	ical or health care decisions on behalf of such-a
3	
4	Øpart of / needed with respect to 2 ÷ for the diagnosis
911	or treatment of the patient. <i>\phimay the patient</i> treat
Ş	then disclose the information (for example, to an
6	other-dector-for-a-second-opinion-vr-to-a
1012	<u> </u>
J	exception, along with any limitations desired;
<u>++13</u>	"(2) Other laws.—Section 1905 of title 18,
12 <u>14</u>	_United States Code, shall not apply with respect to
13 <u>15</u>	the publishing, divulging, disclosure, or making
1416	known of information reported to or otherwise ob-

Commented [SD20]: Senate version uses "legal guardian"; this version uses broader language.

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33
4517 tained by the Administrator under this Act. ** Addict8 ary drafters note that it is unclear what this para9 graph is intended to achieve?
4618 "(i) Applicability.—

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[Discussion Draft]

119

17 <u>19</u>	"(1) IN GENERAL.—Except as otherwise pro-
ļ	wided in this section, \$800 tions section 82 one editocheck this
20	reference ; or any other applicable applica:
<u> </u>	— <u>ble</u> Federal law, the
<u> 1821 </u>	Administrator shall have no authority— <u>au</u>
22	<u>thority—</u>
49 <u>23</u>	"(A) to require the substantiation or re-
2024	substantiation of a claim for the protection
2425	from disclosure of information reported to or

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[Discussion Draft]

34

1	otherwise obtained by the Administrator under
2	this Act prior to the date of enactment of the
3	Frank R. Lautenberg Chemical Safety for the
4	21st Century Act; or
5	"(B) to impose substantiation or re-
6	substantiation requirements—under this Act that, with respect to the
<u>"</u>	protection of information described in sub-
8	section (a), under this Act that are more extensive exten:
3	than those required under
79	this section.
8 <u>10</u>	"(2) Actions prior to promulgation of
911	RULES.—Nothing in this Act prevents the Adminis-
1012	trator from reviewing, requiring substantiation or re-
11-13	substantiation of, or approving, approving in part, or
1214	denying any claim for the protection from disclosure
13 <u>15</u>	of information before the effective date of such rules
4416	applicable to those claims as the Administrator may
4517	promulgate after the date of enactment of the Frank
4618	R. Lautenberg Chemical Safety for the 21st Century

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[Discussion Draft]

1920)

- 1 Act. Othis may be taken care of elsewhere in the bill.
- 3 if so, strike here;
- 19 Act.
- 4720 "(j) Access by Congress.—Notwithstanding any
- 4821 limitation contained in this section or any other provision
- 4922 of law, all information reported to or otherwise obtained
- 2023 by the Administrator (or any representative of the Admin-
- 2424_istrator) under this Act shall be made available, upon writ-

[Discussion-Draft]

1335)

- 1 ten request of any duly authorized committee of the Con-
- 2 gress, to such committee.".

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/5/2016 3:35:13 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: RE: Sen. Markey TSCA TA Request on Section 4(a)(1)

Got it - thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Tuesday, April 05, 2016 11:34 AM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: FW: Sen. Markey TSCA TA Request on Section 4(a)(1)

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey









From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Friday, March 25, 2016 12:04 PM

To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)

Subject: Sen. Markey TSCA TA Request on Section 4(a)(1)

Michal – please see TA below responding to the request on section 4(a)(1). Please let me know if any questions. Thanks,

Sven

Question

In the list of items under senate 4(a)(1) - list of 4 conditions where there is testing allowed by order. In discussing a hybrid House/Senate concept, a question was raised about whether RULES could be required for some or all of the 4(1)(B) items rather than orders. Tell us of any downsides - argument is that epa is already writing a 6(a) rule that may include a restriction related to testing, and same w potentially 5(d). What we'd like is your assessment of scenarios in which a requirement to do rules rather than orders in 4(1)(B) would be a problem. It may be that all scenarios are problems - but it may also be that there are some scenarios where it would not be.

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

- (a) TESTING REQUIREMENTS
- (1) IN GENERAL. The Administrator may, by rule, order, or consent agreement, require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary –
- (A) to review a notice under section 5(d) or to perform a risk evaluation under section 6;
- (B) to implement a requirement imposed in a rule, consent agreement or order issued under section 5(d) or under a rule promulgated under section 6(a);
- (C) pursuant to section 12(a)(4); or
- (D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

EPA Response:

We have a number of concerns with the suggested removal of order authority from all or part of the Senate's Section 4(a)(1).

EPA's difficulty in requiring development of information on chemicals is a major problem under current law. There are two main issues. First, existing law requires EPA to make a risk or exposure finding in order to require testing under Section 4. When data on a chemical is lacking, it is very challenging for EPA to exercise its Section 4 authorities. Second, even if EPA is able to clear the initial Section 4 hurdle, it must then go through a lengthy rulemaking to require the testing and get the data - potentially a 3-5 year process. Continuation of the rulemaking requirement unnecessarily delays EPA from getting the information it needs to assess a chemical's safety, and would almost certainly prevent EPA from meeting statutory deadlines under the House and Senate bills for completing risk evaluations

With respect to the argument you described, it is hypothetically possible that EPA might promulgate a testing requirement concurrently with a section 6(a) or 5(d) rule. But it is also possible that the testing need will not become apparent until the restriction under 5 or 6 is already in place. If successful implementation of a protective requirement is dependent on information to be developed under Section 4, it is imperative that EPA have order authority to require that information in an expeditious manner.

The Administration's Principles very clearly call for EPA to be given "the necessary authority and tools...to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals." The recent Administration's views letter echos that sentiment, commending both the House and Senate for providing EPA with new order authority in Section 4. We'd underscore the importance of order authority again here.

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Wednesday, March 23, 2016 3:48 PM
To: Kaiser, Sven-Erik < Kaiser, Sven-Erik@epa.gov>

Cc: Black, Jonathan (Tom Udall) < Jonathan Black@tomudall.senate.gov>; Deveny, Adrian (Merkley)

<Adrian Deveny@merkley.senate.gov>

Subject: Section 4

Sven

In the list of items under senate 4(a)(1) - list of 4 conditions where there is testing allowed by order. In discussing a hybrid House/Senate concept, a question was raised about whether RULES could be required for some or all of the 4(1)(B) items rather than orders. Tell us of any downsides - argument is that epa is already writing a 6(a) rule that may include a restriction related to testing, and same w potentially 5(d). What we'd like is your assessment of scenarios in which a requirement to do rules rather than orders in 4(1)(B) would be a problem. It may be that all scenarios are problems - but it may also be that there are some scenarios where it would not be.

Thanks M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/28/2016 5:54:04 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: RE: Sen. Markey TSCA TA request on costs analysis

Michal – thanks for letting me know – will pass along. Please let me know if any additional questions. Best, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Thursday, April 28, 2016 1:51 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: Sen. Markey TSCA TA request on costs analysis

On the "category of articles" comment — I understood you guys perfectly and was fine with the House's proposed deletion. Others, however, ALSO understood the impact of the proposed deletion perfectly, and rejected the House proposal.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey









From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Thursday, April 28, 2016 6:36 AM

To: Freedhoff, Michal (Markey)

Subject: RE: Sen. Markey TSCA TA request on costs analysis

Michal.

Resend with both documents attached. Please let me know if any questions. Thank, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753 From: Kaiser, Sven-Erik

Sent: Wednesday, April 27, 2016 9:04 PM **To:** Michal Freedhoff@markey.senate.gov

Subject: Sen. Markey TSCA TA request on costs analysis

Michal,

This TA responds to the request on cost considerations.

In particular, there are three comments to point out. The most important is the comment on p. 49 [44] of the second document (RLSO of HLC 4 22), which addresses the cost analysis issue for alternatives we have discussed.

The other two are on p. 137 [124] of that document (addressing discrepancies in the drafting of section 21) and p. 8 of the first document (suggesting text to align the sec 5 review period with the obligation to respond to information submitted).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/11/2016 1:24:20 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

Subject: Re: Sen. Markey TSCA TA Request on Chem ID

Michal- got it- thanks, Sven

On Apr 11, 2016, at 9:23 AM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

Sven

Getting back to this question from a different direction – your TA below says that there is a 3rd basis for withholding chemID from HS: "where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study."

We have the pre-NOC exclusion in current senate 14

(i) <!--[if !supportLists]--><!--[endif]-->The specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5.

I am wondering if "if the specific identity is not necessary to interpret the HS study" is something that I should be exploring in addition to the other ideas for inclusion alongside process and concentration/proportion. To that end, is there an easy way that you could provide me with some statistics/#s along the following lines (approximate #s ok)

- 1- <!--[if !supportLists]--><!--[endif]-->How many chemID CBI claims are there generally? Per year?
- 2- <!--[if !supportLists]--><!--[endif]-->How many chem IDs are withheld (both generally and per year) from HS studies because releasing would reveal
 - a. <!--[if !supportLists]--><!--[endif]-->Process
 - b. <!--[if !supportLists]--><!--[endif]-->Concentration/proportion
 - c. <!--[if !supportLists]--><!--[endif]-->Pre-NOC AND info not necessary

If this is impossible to figure out in a quick timeframe let me know and maybe we can figure out some other way to answer my question, which is, generally, "what is the actual impact of adding the specific identity is not necessary to interpret the health and safety study" under this EPA's practice.

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Saturday, April 09, 2016 12:19 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA Request on Chem ID

Michal,

This TA responds to the request on chem ID.

Your two emails seem to be asking questions in different directions: the first seems to be asking whether another basis could be added for allowing the withholding of chem id *in health and safety studies* (presumably something industry would want), and the second seems to be asking the very different question of whether there should be more stringent expiration or voiding conditions for chem id *outside the context of health and safety studies* than for other CBI (presumably something the NGOs would want).

Re your first question: although the statute allows for withholding of chem ID (or other info) in health and safety studies only on two bases (reveals process information of proportions of a mixture), EPA regulations allow withholding of specific chem ID on a third basis: where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study. That kind of provision could be codified in the bill.

Re your second question: The idea sounds like a beefing up of sec 14(c)(3) of the Senate offer, which presumptively voids CBI claims for chem ID and other information elements following a ban of a chemical. The triggering event for that provision could be moved up to the finding of unreasonable risk.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks, Sven

From: "Freedhoff, Michal (Markey)" < Michal Freedhoff@markey.senate.gov>

Date: April 9, 2016 at 11:20:40 AM EDT

To: "Kaiser, Sven-Erik" < Kaiser.Sven-Erik@epa.gov > Subject: RE: Sen. Markey TSCA TA request on ChemID

As part of your thought process here, and perhaps as an alternative option, let's think about a way where if chemID is kept CBI it goes public if a) epa makes a section 6 or 7 unreasonable risk finding about it and b) it has to be resubstantiated every 5/10 years with reasonable potential of an unreasonable risk being one of the things EPA has to consider.

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations Office of Senator Edward J. Markey 255 Dirksen Senate Office Building Washington, DC 20510 202-224-2742

On Apr 9, 2016, at 5:40 AM, Freedhoff, Michal (Markey) Michal Freedhoff@markey.senate.gov wrote:

Good morning

We increasingly hear that "molecular structure" is a huge threshold issue for the House. It is for us too. I'm trying to learn more about the history here and also see if there exists middle ground - something akin to a 3rd condition for when chemID is withheld, like "keep molecular structures secret if X or Y, or unless X or Y". I'm not sure if a space like this exists for either side, but thought perhaps looking towards the recent decisions by EPA on why it did or did not release molecular structure could be useful.

Can you put together background materials or suggestions if you have any? Doesn't have to be before 1, but would be helpful if it was before 5 or 6 pm so I can review tonight as part of some of the other prep work I'm planning.

Thanks Michal

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/21/2016 9:34:34 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: Sen. Markey TSCA TA Request on nomenclature language Attachments: Markey.TSCA TA.nomenclature with savings (4-20).docx

Michal.

The attached TA responds to the request on nomenclature language (4-20).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Wednesday, April 20, 2016 6:33 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov >

Subject: Fw: confidential draft

Pls review. Section 6 coming soon.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: McCarthy, David < David McCarthy@mail.house.gov>

Sent: Wednesday, April 20, 2016 6:29 PM

To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff,

Michal (Markey)

Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick

Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"
- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) -
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26
- On page 12 delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below. "(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

On section 8:

Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations — if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule. Keep tiered testing, but tweak it:

"(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall consider employing a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first considering [conducting] screening-level testing.";

$F:\ TB\ B_{892}.XML$

[Discussion Draft]

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

1	.—
2	"(3) Nomenclature.—
3	"(A) In GENERAL.—In carrying out para-
4	graph (1), the Administrator shall—
5	"(i) maintain the use of Class 2 no
6	menclature in use on the date of enact-
7	ment of the Frank R. Lautenberg Chem·
8	ical Safety for the 21st Century Act;
9	"(ii) maintain the use of the Soap and
10	Detergent Association Nomenclature Sys-
11	tem, published in March 1978 by the Ad
12	ministrator in section 1 of addendum III
13	of the document entitle d`Candidate List of
14	Chemical Substances', and further de-
15	scribed in appendix A of volume I of the
16	1985 edition of the Toxic Substances Con-
17	$trolActSubstancesInventory(EPADocu\cdot$
18	ment No. EPA-560/7-85-002a); and
19	"(iii) treat all chemical substances de
20	scribed by the following category listings,
21	when manufactured as described in such
22	appendix, as being included on the list
23	published under paragraph (1) under the

Commented [A1]: EPA TA: The language in (A)(iii) is fine. It simply provides that whether or not a particular chemical substance qualifies as being listed on the inventory under one of these inventory listings depends on how EPA defined the inventory listings at the time EPA established the inventory. This text doesn't resolve one way or the other any dispute about how to construe any of these inventory listings, and it is clear about which inventory listings it is talking about.

Note though that it would be helpful to clarify your drafting intent in the final legislative history. The Senate conference report contains some confusing statements about continuing the current policy of "not requiring notification for variations in . . . mixtures, which (if unaddressed) could influence subsequent interpretation of this passage.

f:\VHLC\041416\041416.026.xml April 14, 2016 (11:03 a.m.) (627653|4)

F:\TB\TB_892.XML	[Discussion Draft]
	2
1	Chemical Abstracts Service numbers for
2	the respective categories:
3	"(I) Cement, Portland, chemi-
4	cals, CAS No. 65997–15–1.
5	"(II) Cement, alumina, chemi-
6	cals, CAS No. 65997–16–2.
7	"(III) Glass, oxide, chemicals,
8	CAS No. 65997–17–3.
9	"(IV) Frits, chemicals, CAS No.
10	65997–18–4.
11	"(V) Steel manufacture, chemi-
12	cals, CAS No. 65997–19–5.
13	"(VI) Ceramic materials and
14	wares, chemicals, CAS No. 66402–
15	68–4.
16	"(B) MULTIPLE NOMENCLATURE CONVEN-
17	TIONS.—
18	"(i) IN GENERAL.—The Administrator
19	shall—
20	"(I) maintain the nomenclature
21	conventions for chemical substances;
22	and
23	"(II) develop new guidance
24	that—

Commented [A2]: EPA TA: Overall, (B) remains problematic. As described below, the savings clause intended to address (B) doesn't currently guard against the problems with (B), and it introduces other problems.

Commented [A3]: EPA TA: This provision requires EPA to "maintain the nomenclature conventions for chemical substances" with no guidance as to what conventions are referred to. The HLC draft suggests that EPA must maintain any nomenclature conventions, whether or not they have been recognized or are considered valid by EPA.

We suggest clarifying which nomenclature conventions you are referring to.

f:\VHLC\041416\041416.026.xml April 14, 2016 (11:03 a.m.) (627653|4)

F:\TB\TB_892.XML	[Discussion Draft]
	3
1	"(aa) establishes equivalency
2	between the nomenclature con-
3	ventions for chemical substances
4	on the list published under para-
5	graph (1); and
6	"(bb) permits persons to
7	rely on the new guidance for pur-
8	poses of <u>identifying</u> determining— whether a
9	chemical substance that is on the list
10	published under paragraph (1).
11	"(ii) Multiple cas numbers.—For
12	a chemical substance determined by the
13	Administrator to appear multiple times on
14	the list in paragraph (1) under different
15	Chemical Abstracts Service numbers, the
16	Administrator shall develop guidance rec
17	ognizing the multiple listings as a single
18	chemical substance.
19	"(C) RELATIONSHIP TO SECTION 5.—
20	"(i) Chemical substances de
21	SCRIBED BY CATEGORIES.—Notwith
22	standing subparagraph (A), a chemical
23	substance that is described by a category
24	listed in subparagraph (A)(iii) shall be
25	subject to section 5 if the chemical sub-

Commented [A4]: EPA TA:

(aa) is limited in scope to chemical substances that are already on the TSCA Inventory.

If your intent is to give (bb) the same scope, it should be conformed to (aa). Under current drafting it seems to be suggesting that different naming conventions could be a pathway for giving a *de facto* Inventory listing to a chemical substance that is not currently listed on the Inventory.

The C(ii) savings clause won't guard against this issue, if (B) isn't fixed, because anyone who thinks that they have a *de facto* Inventory listing under (bb) will simply argue that because they are *de facto* listed on the Inventory, due to (bb), the (C)(ii) savings clause doesn't apply to them.

Also, as noted above, a savings clause that merely specifies that a chemical is "subject to section 5," doesn't pin down whether or not the chemical substance is to be treated as a new chemical substance.

Commented [A5]: EPA TA: If the intent is to provide that such chemicals are considered to be new chemical substances (and thus subject to PMN review), then that would be better stated directly. Simply stating that a chemical is "subject to section 5" doesn't actually establish whether the chemical is a new chemical substance for which a PMN is required. All chemical substances (new and existing) are subject to section 5 because they can be SNUR'd.

f:\VHLC\041416\041416.026.xml April 14, 2016 (11:03 a.m.) (627653|4)

[Discussion Draft]

4

<u> </u>	-stance is not included as an individual
21	<u>ehemical substance individually listed on the</u>
	list published
<u>32</u>	under paragraph (1) as of the date of en
43	_actment of the Frank R. Lautenberg
54	Chemical Safety for the 21st Century Act.
<u>65</u>	"(ii) Chemical substances
7 <u>6</u>	grouped by cas number.—Notwith-
87	standing subparagraph (B), a chemical
98	substance that is not included as an indi-
109	_vidual chemical substance on the list pub-
H <u>10</u>	_lished under paragraph (1) as of the date
1211	_of enactment of the Frank R. Lautenberg
1312	Chemical Safety for the 21st Century Act
1413	shall be subject to section 5.".

Commented [A6]: EPA TA: If the intent is to refer to a chemical substance not individually listed on the inventory, it would be better to say that. A chemical could be said to be included as an individual chemical if it is captured within a broader listing, and yet that is the scenario that you seem to want to exclude here.

Commented [A7]: EPA TA: This breadth of this provision is sweeping: It covers any individual chemical substance that may be present as a constituent of an existing UVCB chemical substance.

This would be important if "shall be subject to section 5" is modified to clearly specify that a new chemical notice is required. In that case, all of the unknown ingredients of all the various UVCBs being manufactured pursuant to UVCB Inventory listings would all suddenly need PMNs if the don't already have individual listings. This would largely undercut the point of having UVCB chemical substances in the first place.

Commented [A8]: EPA TA: As noted above, this doesn't actually clarify whether the chemical is a new chemical or not.



From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 3/16/2016 10:59:39 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

Subject: Re: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Got it-checking along with the last one. Thanks, Sven

On Mar 16, 2016, at 6:46 PM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

<!--[if !supportAnnotations]--> <!--[endif]-->
Does this work for 14(c)(3)(B)

(B) EXCEPTIONS FROM PRESUMPTION

(i) Paragraph (3)(A) shall not apply to any condition of use of a chemical substance for which an exemption under section 6(g) has been granted;

- (ii) For a ban or phase-out of a chemical substance that is not established for all conditions of use of the chemical substance, paragraph (3)(A) shall apply only to information about the chemical substance that relates solely to the conditions of use for which the ban or phase-out is established;
- (iii) Paragraph (3)(A) shall apply to a chemical substance for which a ban or phase-out has been established if the chemical substance continues to be manufactured, processed and distributed solely for export if EPA determines that section 12(a)(1) shall not apply to the chemical substance in accordance with section 12(a)(2). <!-[if !supportAnnotations]-->[MF3]<!-[endif]-->: and
- (iv) Paragraph (3)(A) shall apply to a chemical substance that is subject to a phase out at such time as the phase out is fully implemented.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, March 15, 2016 4:43 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Michal – please see the requested followup TA on CBI and health and safety studies.

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

Response: EPA would interpret the highlighted language to effect no changes in either EPA practice or the Senate passed bill. EPA has always addressed the mix of CBI and non-CBI information in a particular document, assessing what needs to be protected and what does not, which is what the second highlighted text appears to require.

That said, others may argue that the *new* highlighted text does effectuate a change in both the bill and practice. EPA would not interpret (c)(2) as a condition or limitation on (c)(1), because it merely provides that information that is protectable remains protectable even if mixed with non-protectable information, a position EPA already takes. However, the new highlighted text might be argued to indicate that (c)(2) in some way limits or conditions the scope of information releasable pursuant to (c)(1).

Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Tuesday, March 15, 2016 1:16 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov >

Subject: RE: Sen. Markey TSCA TA Request on CBI - health and safety studies

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

- (c) Information Not Protected From Disclosure.—
- (1) IN GENERAL.—Notwithstanding subsections (a) and (b), and subject to paragraph (2), the following information shall not be protected from disclosure:
 - (A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—
 - (i) IN GENERAL.—Subject to clause (ii)—
 - (I) any health and safety study that is submitted under this Act with respect to—
 - (aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or
 - (bb) any chemical substance or mixture for which-
 - (AA) testing is required under section 4; or
 - (BB) a notification is required under section 5; or
 - (II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).
 - (ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—
 - (I) a process used in the manufacturing or processing of a chemical substance or mixture; or
 - (II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.
 - (B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:
 - (i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).
 - (ii) A safety assessment developed, or a safety determination made, under section 6.

- (iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.
- (iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.
- (2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Michal Ilana Freedhoff, Ph.D.
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202-224-2742

Connect with Senator Markey

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, March 15, 2016 1:13 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA Request on CBI - health and safety studies

Michal.

This responds to your TA request on CBI and health and safety studies.

Question: Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

EPA Response: The companies provide a sanitized version of the submission which is what we publish, assuming no final determination has been made regarding eligibility for confidential treatment.

Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Tuesday, March 15, 2016 10:32 AM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: TA - health and safety studies

Sven

Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

Thx M

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

<!--[if !supportAnnotations]-->

<!--[endif]-->

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/19/2016 9:03:05 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall)

[Jonathan_Black@tomudall.senate.gov]

Subject: Sen. Markey TSCA TA Request on partial REs

Michal – got it. Will circulate for response. In the queue between 5 and 26, unless would derail 26. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Tuesday, April 19, 2016 5:01 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall)

<Jonathan_Black@tomudall.senate.gov>

Subject: partial REs

For after you finish with 5, and only if it is not going to delay you sending 26 (it is a 26 issue).

I am wondering if this is why House keeps baking least burdensome back into the partial RE language in 26. I'm not at all interested in the suggested CSAC approach as it won't exist in the right timeframe. I'd be interested in your thoughts on the IQA idea, but am thinking it probably makes sense to cite to the science language in 26 in the partial RE section and be done. I'd be interested in your thoughts

michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 3/2/2016 5:29:07 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall)

[Jonathan Black@tomudall.senate.gov]

Subject: RE: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal – got it – checking on availability. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Wednesday, March 02, 2016 12:28 PM **To:** Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Cc: Deveny, Adrian (Merkley) <Adrian Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall)

<Jonathan_Black@tomudall.senate.gov>

Subject: RE: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Adding Adrian and Jonathan

There is ZERO interest in preserving the problem you're describing below. We are attempting to eliminate that problem. We have text we did not have when I first sent the question in that I am pasting excerpts of below so you can understand what we are thinking about. We'd like to schedule a call with you guys this afternoon between 1:30-4:30 (perhaps with other folks as well) so we can resolve this. Does that work?

Michal

(4) RISK EVALUATION PROCESS AND DEADLINES.—

- (A) Not later than 1 year after enactment, the Administrator shall establish, by rule, a process to conduct risk evaluations in order to determine, without consideration of costs or other non-risk factors, whether a high-priority chemical substance presents an unreasonable risk of injury to health or the environment from exposure to the chemical substance under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant to the risk evaluation by the Administrator.
- (B) The Administrator shall conduct and publish a risk evaluation, in accordance with the rule promulgated under subparagraph (A), for a chemical substance—
 - (i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and
 - (ii) subject to subparagraph (D), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (A), be subjected to a risk evaluation.
- (C) The Administrator shall, as soon as practicable and not later than 6 months of each designation of a high priority substance, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible populations the Administrator expects to consider.
- "(E) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

- "(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible populations identified as relevant by the Administrator;
- "(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use was considered, and the basis for that consideration;
- "(iii) not consider information on cost and other factors not directly related to health or the environment;
- "(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and
- "(v) describe the weight of the scientific evidence for the identified hazard and exposure.

c) PROMULGATION OF SUBSECTION (a) RULES.

- (1) If, based on a risk evaluation conducted in accordance with the rule promulgated under subsection (b)(4)(A[MVL1]), the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, , the Administrator—
 - (A) shall propose a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

Michal Ilana Freedhoff, Ph.D.
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Wednesday, March 02, 2016 12:09 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michai

This responds to your TA request on risk evaluations and unreasonable risk. Please let me know if any additional questions. Thanks, Sven

Although there is too little detail to evaluate definitively, we have significant concerns with this proposed construct.

As you've described it, all risk management rules would still be subject to the current TSCA unreasonable risk standard, and EPA would still be limited by the same cost-benefit balancing analyses that have prevented effective action on chemicals in the past.

We also don't see the value in requiring EPA to issue a rule regarding risk evaluation with a preordained outcome: don't consider cost or other non-risk factors. This process will consume a significant amount of EPA time and resources, and delay the business of evaluating chemicals and protecting against identified risks. If Congress wants to preclude EPA from considering such factors in this context, the far more direct way to do so is by statutory directive.

Finally, if EPA is required to act by rule, commenters (and litigants) will likely argue that Congress must have intended EPA to have some discretion in the rulemaking, and will likely point to the authority to consider cost

as part of the risk management rulemaking to argue that EPA should be able to factor cost in some fashion into the underlying safety standard. As such, this proposed approach seems likely to leave unsettled for a protracted period of time the most significant TSCA policy shift made in both bills.

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Tuesday, March 01, 2016 4:53 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov > **Subject:** Section 6 - quick unreasonable risk q

Here is a construct being discussed:

- 1) epa promulgates a rule for how risk evaluations are supposed to be conducted study a chemical to decide whether it poses an unreasonable risk, and don't consider costs/non-risk factors the unreasonable risk "fix" is made in the rule itself.
- 2) later in the section, we tell people to conduct a risk evaluation in accordance with the rule above, in order to figure out whether the substance poses an unreasonable risk, but I do NOT remove cost consideration in this place because of the reference to the RULE, which does require the fix.

Any concerns with this description re "unreasonable risk"?

Thanks Michal

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/15/2016 4:42:25 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

Subject: Re: Sen. Markey TSCA TA on Jackie's 6

Got it- thanks

On Apr 15, 2016, at 12:41 PM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

Also pls look at her new "low hazard" thing in 6.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik

Sent: Friday, April 15, 2016 12:25 PM **To:** Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA on Jackie's 6

Michal,

This TA responds to the request on Jackie's draft section 6., re: the alternatives analysis language, p11, line 5.

This language is consistent with the type of analysis that EPA would already do in the absence of statutory mandate, and we do not see a significant issue with it. That being said, one way to soften the requirement would be to replace "determine" (p.11, line 10) with "consider." See text below. Doing so would reduce opportunities for litigation on the sufficiency of EPA's "determination" – a separate administrative action that can be challenged.

"(C) based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, determine consider whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect;

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Freedhoff, Michal (Markey)" < <u>Michal Freedhoff@markey.senate.gov</u>>

Date: April 15, 2016 at 10:29:08 AM EDT

To: "Kaiser, Sven-Erik" < <u>Kaiser.Sven-Erik@epa.gov</u>>

Subject: Re: Jackie's 6

Also pls see alternatives analysis p 11 line 5. We need to include something like this. Need this back asap. I was hoping to limit this language to bans and phaseouts but in the past you've said you would do this analysis anyway and want your take on this.

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik

Sent: Friday, April 15, 2016 10:23 AM

To: Freedhoff, Michal (Markey)

Subject: Re: Jackie's 6

Got it - checking

On Apr 15, 2016, at 10:22 AM, Freedhoff, Michal (Markey) < Michal_Freedhoff@markey.senate.gov > wrote:

On section 6 pls esp look at p 10 lines 14 and on. And rank on the chart? Asap would be good.

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

<Jackie section 6.pdf>

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/23/2016 10:30:07 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall)

[Jonathan Black@tomudall.senate.gov]

Subject: Re: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal - no issues with the edits. Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460

202-566-2753

On Apr 23, 2016, at 6:13 PM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

Ty - any issues w these edits?

- <!--[if !supportLists]--><!--[endif]-->Page 150 line 19 Insert "the date on which" before "an order"
- <!--[if !supportLists]--><!--[endif]-->Page 150 line 19 Insert "is issued" after "an order"

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202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Saturday, April 23, 2016 6:12 PM

To: Freedhoff, Michal (Markey)

Cc: Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall) **Subject:** Re: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal.

Revised TA on section 19 with house changes annotated.

Section 19 – Sec. 19.XML comments

Page 1 – remove all brackets DONE

Page 1 line 6 to 19 -- consolidate this material in paragraph (a)(1), perhaps as a new (a)(1)(C). Per EPA TA to ensure that low priority decisions are covered by the judicial review provisions of subsection (c). DONE

Page 2 line 9 – remove brackets from "Except as otherwise provided by this title" DONE

Page 2 line 13 – remove brackets from "6(i)(1)" DONE

Page 2 lines 18 to 25 – remove all brackets DONE

Page 3 line 6 – remove brackets from "6(i)(1)" DONE

Page 4, line 2– strike lines 2 through 21, and insert:

"by amending subsection (c)(1)(B)(i) to read: "(i) in the case of review of a rule under section 4(a), 5(b)(4), 6(a) (including review of the associated determination under section 6(b)(4)(A)) or 6(e), or an order under 6(i)(1) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule or order if the court finds that the rule or order is not supported by substantial evidence in the record including any matter in the record taken as a whole;" DONE EXCEPT SUBSTANTIAL EVIDENCE DIRECTION FOR RULES AND ORDERS IS DIVIDED INTO SEPARATE SUBCLAUSES AND REVIEW OF TEST ORDERS UNDER SECTION 4 IS ADDED TO SUBSTANTIAL EVIDENCE REVIEW.

Page 5 line 7-8 – Strike the brackets before (iii) DONE

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460

On Apr 23, 2016, at 4:30 PM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

Just verifying before proceeding that you checked conforming edits at the end of the bill?

Michal Ilana Freedhoff, Ph.D.
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<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Saturday, April 23, 2016 4:29 PM

To: Freedhoff, Michal (Markey); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)

Subject: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal,

While we continue to work on the TA requests on 14 and other sections, we wanted to pass along TA on house section 19 (4-23).

The House discussion draft leaves section 19 from current TSCA un-amended, except for the addition of judicial review of low-priority determinations. Thus, in contrast to the Senate bill and offer, it does not:

- -- provide for judicial review of test orders under section 19
- -- provide for judicial review of rules other than the rules currently enumerated in section 19
- -- provide for judicial review of determinations that a chemical substance does not present unreasonable risk under section 19 (including the substantial evidence review the senate bill and offer would afford).

Note that this does not mean that these EPA actions will not be judicially reviewable. Rather, they would be reviewable in federal district court, rather than the court of appeals, and would be subject to the general federal 6-year review period, rather than the 60 days provided for in section 19.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/5/2016 3:25:19 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

Subject: Re: Sen. Markey TSCA TA on house Section 4

Michal- we're not sure that house 4 is so bad. The adds at the end might save it. Can you call again Lex 6-Personal Privacy

Ex. 6 - Personal Privacy

On Apr 5, 2016, at 10:29 AM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

Thank you, ai am re-drafting yet another section 4, pls stand by for that in the next hour or so I hope.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
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Washington, DC 20510
202-224-2742

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<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, April 05, 2016 10:26 AM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA on Section 5 - early morning

Michal – TA responding to your comments on section 5 attached. EPA comments in blue. Please let me know if any questions. Thanks

if any questions. Thanks,

Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Tuesday, April 05, 2016 6:00 AM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: Fw: Section 5

Sven - comments in yellow are for you, changes marked with blank comment boxes and a couple in green for Dimitri. Pls take one more FAST look, need to get this to the House asap.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)



From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/13/2016 6:59:26 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: Sen. Markey TSCA TA Request on Chem ID

Michal.

This TA responds to the request on chem ID.

Here are the regulations governing CBI claims for the identity of chemical substances contained in health and safety studies where those substances are the subject of Premanufacture Notices under Section 5. Those regulations, at 40 CFR 720.90, contain an exception from disclosure where the specific chemical identity is not necessary to interpret a health and safety study. See 720.90(c):

- (c) Denial of confidentiality claim. EPA will deny a claim of confidentiality for chemical identity under paragraph (b) of this section, unless:
- (1) The information would disclose processes used in the manufacture or processing of a chemical substance or mixture.
- (2) In the case of a mixture, the information would disclose the portion of the mixture comprised by any of the substances in the mixture.
 - (3) The specific chemical identity is not necessary to interpret a health and safety study.

For your reference, EPA's general TSCA confidentiality regulations at 40 CFR 2.306 do not include this exception from disclosure of information from health and safety studies, and EPA's regulations regarding health and safety studies submitted under TSCA section (8)(d) at 40 CFR part 716 state that chemical identity is part of, or underlying data to, a health and safety study. 40 CFR 716.3.

Also, per request, here is a proposed revision of the most recent language you provided regarding health and safety studies in section 14(b)(1). This would provide protection for confidential chemical identities contained in health and safety studies of uncommenced PMNs substances, but eliminate such special protection once manufacture or processing has commenced such that the chem IDs would be releasable at that point unless they meet one of the two statutory bases for withholding (process information and proportions-of-mixtures information).

(b) Information Not Protected From Disclosure.—

- "(1) DATA FROM HEALTH AND SAFETY STUDIES.—Subsection (a) does not prohibit the disclosure of—
- (A) any health and safety study which is submitted under this chapter with respect to—
- (i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or
- (ii) any chemical substance or mixture for which testing is required under section 2603 of this title or for which notification is required under section 2604 of this title, and

(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture—or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture, or the specific identity of a chemical substance or mixture for which notification is required under section 2604 of this title and which has not been offered for commercial distribution.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Wednesday, April 13, 2016 11:14 AM **To:** Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: ChemID question

Can you send me the regulations for how epa decides when to protect chemID in a health and safety study when it does NOT fall into the process/concentrations categories that allow protection? I'm trying to understand how epa decides these cases that are not automatically protected in HS studies - is it case by case? On what basis?

Thanks

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/2/2016 2:09:35 AM

To: 'McCarthy, David' [David.McCarthy@mail.house.gov]

Subject: HEC TSCA TA on House 6(c)(1)(B)

Dave,

This TA responds to the request on 6(c)(1)(B). Please let me know if any questions. Thanks, Sven

TA Request: Impact of draft 6(c)(1)(B) including adding "reasonably"

House bill "(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are reasonably necessary to protect against the identified risk."

Response: We believe the addition of "reasonably" probably marginally reduces the burden on EPA to demonstrate that non-cost-effective requirements are necessary.

That said, this addition does not address the other points EPA has made in technical assistance on this provision. Specifically:

- 1. The provision states that EPA's determination of cost-effectiveness must be "consistent with the information published under subparagraph (A)". We do not believe that clearly circumscribes the extent of the information EPA must assess in judging cost-effectiveness. If the intention is to provide that the information EPA is required to assess in assessing cost-effectiveness is limited to the information published under subparagraph (A), it would be clearer if the provision stated that the determination must be "based on the information published under subparagraph (A)."
- 2. On a related issue, the scope of the analysis EPA would be required to undertake is unclear. Since EPA can impose non-cost-effective requirements only where such requirements are necessary (or reasonably necessary), it could be argued that EPA could not make such a showing without first identifying and rejecting all possible cost-effective requirements.
- 3. The protectiveness standard in the provision "[reasonably] necessary to protect against the identified risk" is different from the protectiveness standard in section 6(a) of the House bill. Thus, it could be argued that the standard when EPA imposes non-cost-effective requirements is in some way different from the general section 6(a) rulemaking standard.

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/8/2016 8:00:05 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: Sen. Markey TSCA TA Section 19
Attachments: Markey.TSCA TA.section 19.4.8.16.doc

Michal.

This TA responds to the request on section 19. We don't see any inconsistency between TA we sent to you and TA we sent to Dmitri. In any event, attached is our TA on the revised section you sent.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: "Freedhoff, Michal (Markey)" < Michal Freedhoff@markey.senate.gov>

Date: April 7, 2016 at 8:43:34 PM EDT

To: "Sven-Erik Kaiser (<u>Kaiser.Sven-Erik@epamail.epa.gov</u>)" < <u>Kaiser.Sven-Erik@epamail.epa.gov</u>> **Cc:** "Karakitsos, Dimitri (EPW)" < <u>Dimitri Karakitsos@epw.senate.gov</u>>, "Deveny, Adrian (Merkley)"

<a href="mailto:

<a href="mailto:

<Jonathan Black@tomudall.senate.gov>

Subject: Section 19

Sven

I'm having trouble reconciling the TA you sent Dimitri (pasted below) with the TA you sent me when I asked for the rest of the Senate-offer conforming changes to 19 (attached). You sent me some changes to cross-refs in the same section of text that you helped Dimitri with, and the cross-references don't seem to match up or maybe I am misunderstanding. Could you take a look at this whole section, with particular attention paid to the yellow highlighted text?

Thanks

Michal

The TA you sent Dimitri:

That said, option 1 is largely harmless if properly edited. To be consistent with the overall structure of the Senate bill, it should read: "section 4(a), 6(d) (including review of <u>the</u> associated determination under section 6(c)(1)(B)), or $6(\underline{\mathbf{h}})$, or an order under section 6(c)(1)(A)." The definite article is to maintain consistency with 6(f)(2), which refers to "the associated safety assessment and safety determination." Referring to "an associated determination" could



This language is provided EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

SEC. 19. JUDICIAL REVIEW.

- (a) In GENERAL.—(1)(A) Except as otherwise provided in this title. Nnot later than 60 days after the date of the promulgation of a rule under this title section 4(a), 5(a)(2), 5(b)(4), 6(a), 4(a), 5(d), 6(c), 6(d), 6(ge), or 8, or under title II or IV, or an order under section 4 or 6(i)(1), any person may file a petition for judicial review of such rule or order with the United States Court of Appeals for the District of Columbia Circuit the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of such a rule or order if any district court of the United States would have had jurisdiction of such action but for this subparagraph.
 - (B) Except as otherwise provided in this title. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of an order issued under this title other than an order under section 4 or 6(i)(1) subparagraph (A) or (B) of section 6(b)(1) if any district court of the United States would have had jurisdiction of such action but for this subparagraph.
- (2) Copies of any petition filed under paragraph (1)(A) shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of title 28, United States Code, shall apply to the filing of the rulemaking—record of proceedings on which the Administrator based the rule or order being reviewed under this section and to the transfer of proceedings between United States courts of appeals.
 - (3) JUDICIAL REVIEW OF LOW-PRIORITY DESIGNATIONS
 - (A) IN GENERAL.—Not later than 60 days after the publication of a designation under section 6(b)(1)(B)(ii), any person may commence a civil action to challenge the designation.
 - (B) JURISDICTION.—The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this paragraph.
- (3) For purposes of this section, the term "rulemaking record" means—
 - (A) the rule being reviewed under this section:
 - (B) in the case of a rule under section 4(a), the finding required by such section, in the case of a rule under section 5(b)(4), the finding required by such section, in the case of a rule under section 6(a) the finding required by section 5(f) or 6(a), as the case may be, in the case of a rule under section 6(a), the statement required by section 6(c)(1), and in the case of a rule under section 6(e), the findings required by paragraph (2)(B) or (3)(B) of such

Commented [A1]: "or for" is missing after "Circuit". Why is the base text not just copied from TSCA? We have not carefully reviewed base text.

Commented [A2]: It would be better to consolidate this into (a)(1). Aside from the unnecessary extra paragraph, the placement of this in a separate paragraph means review of low priority decisions is not covered by the judicial review provisions of (c). That's probably ok, but is there any reason for that?

[PAGE]

This language is provided EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

section, as the case may be and in the case of a rule under title IV, the finding required for the issuance of such a rule.

- (C) any transcript required to be made of oral presentations made in proceedings for the promulgation of such rule;
- (D) any written submission of interested parties respecting the promulgation of such rule; and
- (E) any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of such rule, in a notice published in the Federal Register.
- (b) Additional Submissions and Presentations; Modifications.— If in an action under this section to review a rule, or an order under section 4 or 6(i)(1), the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule or order and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule or order being reviewed or make a new rule or order by reason of the additional submissions and presentations and shall file such modified or new rule or order with the return of such submissions and presentations. The court shall thereafter review such new or modified rule or order.
- (c) STANDARD OF REVIEW.—(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of a rule or order, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5, United States Code, and (ii) except as otherwise provided in subparagraph (B), to review such rule in accordance with chapter 7 of title 5, United States Code.
 - (B) Section 706 of title 5, United States Code, shall apply to review of a rule under this section, except that—
 - (i) in the case of review of a rule under section 4(a), 6(a) (including review of the associated determination under section 6(c)(1)(B)), or 6(e), or an order under section 6(i)(1), 4(a), 5(b)(4), 6(a), or 6(e), the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule or order if the court finds that the rule or order is not supported by substantial evidence (including any matter) in the rulemaking record, (as defined in subsection (a)(3)) taken as a whole; and

(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be

Commented [A3]: The citations in this document seem to be to the senate offer, except for this one, which seems to be to the senate bill. If you are working off the senate offer, this citation should presumably be to 6(b)(4)(A).

[PAGE]

⁴⁻So in law. Probably should be followed by a comme.

This language is provided EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

incorporated in the rule or order, except as part of the rulemaking record, taken as a whole.

(I) a determination by the Administrator under section 6(c)(3) that the petitioner seeking review of such rule is not entitled to conduct (or have conducted) cross-examination or to present rebuttal submissions, or

(II) a rule of, or ruling by the Administrator under section 6(c)(3) limiting such petitioner's cross-examination or oral presentations;

has precluded disclosure of disputed material facts which was necessary to a fair determination by the Administrator of the rulemaking proceeding taken as a whole; and section 706(2)(D) shall not apply with respect to a determination, rule, or ruling referred to in subclause (I) or (II); and

(iii) the court may not review the contents and adequacy of

(1) any statement required to be made pursuant to section 6(c)(1), or

(II) any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule

except as part of a review of the rulemaking record taken as a whole.

The term "evidence" as used in clause (i) means any matter in the rulemaking record.

- (C) A determination, rule, <u>order</u>, or ruling of the Administrator described in subparagraph (B)(ii) may be reviewed only in an action under this section and only in accordance with such subparagraph.
- (2) The judgment of the court affirming or setting aside, in whole or in part, any rule or order reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.
- (d) FEES AND COSTS.—The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.
- (e) Other Remedies.—The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law. [15 U.S.C. 2618]

Commented [A4]: It is probably harmless to retain this, but it is superfluous and could be conflusing. This is adapted from current TSCA, which applies to both the 553(c) statement and the statement require by current TSCA 6(c). The latter provision has been deleted from the bill and hence deleted from this clause. This clause is presented as an exception to the APA, but it's now not an exception: the statement of basis and purpose required by the APA is only reviewable as part of the record as a whole even without this provision. If this is to be retained, it would be better as a free-standing (superfluous) provision, rather than being presented as an exception to the

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/28/2016 10:36:29 AM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: RE: Sen. Markey TSCA TA request on costs analysis

Attachments: Markey.TSCA TA.Costs Analysis.Senate Offer 4 24 RLSO of HLC 4 22.docx; Markey.TSCA TA.Costs Analysis.Senate

Offer 4.24 - Section 5.docx

Michal.

Resend with both documents attached. Please let me know if any questions. Thank,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik

Sent: Wednesday, April 27, 2016 9:04 PM **To:** Michal_Freedhoff@markey.senate.gov

Subject: Sen. Markey TSCA TA request on costs analysis

Michal,

This TA responds to the request on cost considerations.

In particular, there are three comments to point out. The most important is the comment on p. 49 [44] of the second document (RLSO of HLC 4 22), which addresses the cost analysis issue for alternatives we have discussed.

The other two are on p. 137 [124] of that document (addressing discrepancies in the drafting of section 21) and p. 8 of the first document (suggesting text to align the sec 5 review period with the obligation to respond to information submitted).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

[DISCUSSION DRAFT]

114TH CONGRESS 2D SESSION

H. R. ||

To ømodernize the Toxic Substances Control Act, and for other purposes ¿.

IN THE HOUSE OF REPRESENTATIVES

Ml. |||||||introduced the following bill; which was referred to the Committee on |||||||||||||||

A BILL

To ømodernize the Toxic Substances Control Act, and for other purposes;.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) SHORT TITLE.—This Act may be cited as the
- 5 "Frank R. Lautenberg Chemical Safety for the 21st Cen-
- 6 tury Act".
- 7 (b) Table of Contents.—The table of contents of
- 8 this Act is as follows:
 - Sec. 1. Short title; table of contents.
 - Sec. 2. Findings, policy, and intent.
 - Sec. 3. Definitions.

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- Sec. 4. Testing of chemical substances and mixtures.
- Sec. 5. Manufacturing and processing notices.
- Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.
- Sec. 7. Imminent hazards.
- Sec. 8. Reporting and retention of information.
- Sec. 9. Relationship to other Federal laws.
- Sec. 10. Exports of elemental mercury.
- Sec. 11. Confidential information.
- Sec. 12. Penalties.
- Sec. 13. State Federal relationship.
- Sec. 14. Judicial review.
- Sec. 15. Citizens' civil actions.
- Sec. 16. Citizens' petitions.
- Sec. 17. Studies.
- Sec. 18. Administration of the Act.
- Sec. 19. State programs.
- Sec. 20. Conforming amendments.
- Sec. 21. No retroactivity.
- Sec. 22. Trevor's Law.
- 1 SEC. 2. FINDINGS, POLICY, AND INTENT.
- 2 Section 2(c) of the Toxic Substances Control Act (15)
- 3 U.S.C. 2601(c)) is amended by striking "proposes to
- 4 take" and inserting "proposes as provided".
- 5 SEC. 3. DEFINITIONS.
- 6 Section 3 of the Toxic Substances Control Act (15
- 7 U.S.C. 2602) is amended—
- 8 (1) by redesignating paragraphs (4) through 9
 - (14) as paragraphs (5), (6), (8), (9), (10), (11),
- 10 (13), (14), (15), (16), and (17), respectively;
- 11 (2) by inserting after paragraph (3) the fol-
- lowing:
- "(4) The term 'conditions of use' means the cir-
- 14 cumstances, as determined by the Administrator, under
- 15 which a chemical substance is intended, known, or reason-

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1	ably foreseen to be manufactured, processed, distributed
2	in commerce, used, and or disposed of.";
3	(3) by inserting after paragraph (6), as so re-
4	designated, the following:
5	$\hbox{``(7)} The term \hbox{`guidance'} means any significant writ\cdot$
6	ten guidance of general applicability prepared by the Ad $$
7	ministrator."; and
8	(4) by inserting after paragraph (11), as so re-
9	designated, the following:
10	"(12) The term 'potentially exposed or susceptible
11	subpopulation' means a group of individuals within the $$
12	general population identified by the Administrator who,
13	due to either greater susceptibility or greater exposure, $% \left(x\right) =\left(x\right) \left(x\right) $
14	may be at greater risk than the general population of ad-
15	$verse\ health\ effects\ from\ exposure\ to\ a\ chemical\ substance$
16	or mixture, such as infants, children, pregnant women, $% \left(n_{x}^{2}\right) =n_{x}^{2}$
17	workers, or the elderly.".
18	SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIX-
19	TURES.
20	Section 4 of the Toxic Substances Control Act (15 $$
21	U.S.C. 2603) is amended—
22	(1) by striking "standards" each place it ap-
23	pears and inserting "protocols and methodologies";
24	(2) in subsection (a)—

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1	(A) by striking "If the Administrator
2	finds" and inserting "(1) If the Administrator
3	finds";
4	(B) in paragraph (1), as so designated—
5	(i) by striking "(1)(A)(i)" and insert
6	ing "(A)(i)(I)";
7	(ii) by striking "(ii)" each place it ap
8	pears and inserting "(II)";
9	(iii) by striking "are insufficient data"
10	and inserting "is insufficient information"
11	each place it appears;
12	(iv) by striking "(iii)" each place it
13	appears and inserting "(III)";
14	(v) by striking "such data" and in-
15	serting "such information" each place it
16	appears;
17	(vi) by striking "(B)(i)" and inserting
18	"(ii)(I)";
19	(vii) by striking "(I)" and inserting
20	"(aa)";
21	(viii) by striking "(II)" and inserting
22	"(bb)";
23	(ix) by striking "(2)" and inserting
24	"(B)"; and

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[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 5 1 (x) in the matter following subparagraph (B), as so redesignated— 2 (I) by inserting ", or, in the case 3 of a chemical substance described in subparagraph (A)(i), by 5 rule order," after "rule"; and 6 (II) by striking "data" each place 7 8 it appears and inserting "information"; and 9 (C) by adding at the end the following: 10 "(2) Additional testing authority.—In 11 addition to the authority provided under paragraph 12 13 (1), the Administrator may, by rule, order, or con-14 sent agreement-"(A) require the development of new infor-15 16 mation relating to a chemical substance or mixture if the Administrator determines that the 17 information is necessary— 18 "(i) to review a notice under section 19 5(d) or to perform a risk evaluation under 20 section 6(b); 21 "(ii) to implement a requirement im-22 23 posed in a rule, order, or consent agree-

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ment under subsection (e) or (f) of section

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	6	
1	5 or under a rule promulgated under sec-	
2	tion 6(a); or	
3	"(iii) at the request of a Federal im-	
4	plementing authority under another Fed·	
5	eral law, to meet the regulatory testing	
6	needs of that authority with regard to tox	
7	icity and exposure; and	
	(iv) 12(a)(2) testing authority	Commented [A1]: Wording needs fixing.
8	"(B) require the development of new infor-	
9	mation for the purposes of prioritizing a chem-	
10	ical substance under section 6(b) only if the Ad-	
11	ministrator determines that such information is	
12	necessary to establish the priority of the sub-	
13	stance, subject to the limitations that—	
14	"(i) not later than 90 days after the	
15	date of receipt of information regarding a	
16	chemical substance complying with a rule,	
17	order, or consent agreement under this	
18	subparagraph, the Administrator shall des	
19	ignate the chemical substance as a high-	
20	priority substance or a low-priority sub-	
21	stance; and	
22	"(ii) information required by the Ad-	
23	ministrator under this subparagraph shall	
24	not be required for the purposes of estab-	
25	lishing or implementing a minimum infor-	

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1	mation requirement of broader applica-
2	bility.
3	"(3) STATEMENT OF NEED.—When requiring
4	the development of new information relating to a
5	chemical substance or mixture under paragraph (2),
6	the Administrator shall identify the reasonable basis for concern about the chemical substance or mixture and the need for the ${\bf new}$
7	information, describe how information reasonably
8	available to the Administrator was used to inform
9	the decision to require new information, explain the
10	basis for any decision that requires the use of
11	vertebrate animals, and, as applicable, explain why
12	issuance of an order is warranted instead of promul-
13	gating a rule or entering into a consent agreement.
14	"(4) Tiered testing.—When requiring the
15	development of new information under this sub-
16	section, the Administrator shall consider employing
17	a tiered screening and testing process, under which
18	the results of screening level tests or assessments of
19	available information inform the decision as to
20	whether 1 or more additional tests are necessary,
21	unless information available to the Administrator
22	justifies more advanced testing of potential health or
23	environmental effects or potential exposure without
24	first considering conducting; screening level test
25	ing.";
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1 (3)	in subsection (b)—
2	Insert (A) in the header to subsection (b), insert ",order or consent agreement" and renumber (A) and subsequent paragraphs accordingly
3	(A) in paragraph (1)—
4	(i) in subparagraph (B), by striking
5	"test data" and inserting "information";
6	(ii) in subparagraph (C), by striking
7	"data" and inserting "information"; and
8	(iii) in the matter following subpara-
9	graph (C), by striking "data" and insert-
10	ing "information";
11	(B) in paragraph (2)—
12	(i) in subparagraph (A)—
13	(I) by striking "test data" and
14	inserting "information";
15	(II) by inserting "Protocols and
16	methodologies for the development of
17	information may also be prescribed
18	for the assessment of exposure or ex-
19	posure potential to humans or the en·
20	vironment." after the first sentence;
21	and
22	(III) by striking "hierarchical
23	tests" and inserting "tiered testing";
24	and
25	(ii) in subparagraph (B), by striking

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Commented [A2]: Can't follow heading designations but substance seems fine

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"data" and inserting "information";

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1	(C) in paragraph (3)—
2	(i) by striking "data" each place it
3	appears and inserting "information"; and
4	(ii) by striking " $(a)(1)(A)(ii)$ or
5	(a)(1)(B)(ii)" each place it appears and in-
6	serting $\text{``(a)(1)(A)(i)(II)}$ or
7	(a)(1)(A)(ii)(II)"; and (iii) in subparagraph (3)(A), insert "or order" after "rule"; (iv) following "subparagraph (B)" insert "or (C), as applicable," (v) at the end of subparagraph (3)(B), in the matter before (3)(B)(i), strike "subsection (a)" and insert "subsection (a)(1)"; and (vi) at the end of subparagraph (3)(B), insert "(C) a rule or order under subsection (a)(2) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order." "(C) A rule or order under subsection (a)(2) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order." This would require several minor conforming changes to (b)(3).
8	(D) in paragraph (4)—
9	(i) by striking "of data" each place it
10	appears and inserting "of information";
11	and
12	(ii) by striking "test data" each place
13	it appears and inserting "information";
14	and
15	(E) by striking paragraph (5);
16	(4) in subsection (c)—
17	(A) in paragraph (1), by striking "data"
18	and inserting "information";

(B) in paragraph (2), by striking "data" $\,$

19

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F:\KML\114\EC\TSCA\2016_02.XML [Discussion Draft] 1 20 each place it appears and inserting "information"; 21 tion"; 22 (C) in paragraph (3)— 23 (i) by striking "test data" each place 24 it appears and inserting "information"; 25 and

[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 10 1 (ii) by striking "such data" each place it appears and inserting "such informa-2 tion"; and 3 (D) in paragraph (4) by striking "test 5 data" each place it appears and inserting "information"; 6 (5) in subsection (d)— 7 (A) by striking "test data" each place it 8 9 appears and inserting "information"; (B) by striking "such data" each place it 10 appears and inserting "such information"; and 11 (C) by striking "for which data have" and 12 inserting "for which information has"; 13 (6) in subsection (e)— 14 (A) in paragraph (1)— 15 16 (i) in subparagraph (A)— (I) by striking "promulgation of 17 a rule" and inserting "development of 18 information"; and 19 (II) by striking "data" each place 20 21 it appears and inserting "information"; and 22 23 (ii) in subparagraph (B), by striking "either initiate a rulemaking proceeding 24

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under subsection (a) or if such a pro-

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1	ceeding is not initiated within such period,
2	publish in the Federal Register the Admin
3	istrator's reason for not initiating such a
4	proceeding" and insert "issue an order,
5	enter into a consent agreement, or initiate
6	a rulemaking proceeding under subsection
7	(a), or, if such an order or consent agree-
8	ment is not issued or such a proceeding is
9	not initiated within such period, publish in
10	the Federal Register the Administrator's
11	reason for not issuing such an order, en-
12	tering into such a consent agreement, or
13	initiating such a proceeding"; and
14	(B) in paragraph (2)(A)—
15	(i) by striking "eight members" and
16	inserting "ten members"; and
17	(ii) by adding at the end the fol-
18	lowing:
19	"(ix) One member appointed by the Chairman
20	of the Consumer Product Safety Commission from
21	${\bf Commissioners or employees of the Commission.}$
22	"(x) One member appointed by the Commis-
23	sioner of Food and Drugs from employees of the
24	Food and Drug Administration.";
25	(7) in subsection (f)—

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use of vertebrate animals in the testing of chemical

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25 substances or mixtures under this title by—

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1	"(A) when making a request or adopting a
2	requirement for testing using vertebrate ani-
3	mals, and in accordance with subsection (a)(3),
4	taking into consideration, as appropriate and to
5	the extent practicable and scientifically justi-
6	fied, reasonably available existing information,
7	including—
8	"(i) toxicity information;
9	"(ii) computational toxicology and
10	bioinformatics; and
11	"(iii) high-throughput screening meth-
12	ods and the prediction models of those
13	methods; and
14	"(B) encouraging and facilitating—
15	"(i) the use of scientifically valid test
16	methods and strategies that reduce the use
17	of vertebrate animals while providing infor-
18	mation of equivalent or better scientific
19	quality and relevance that will support reg-
20	ulatory decisions under this title;
21	"(ii) the grouping of 2 or more chem-
22	ical substances into scientifically appro-
23	priate categories in cases in which testing
24	of a chemical substance would provide sci-
25	entifically valid and useful information on

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1	other chemical substances in the category;
2	and
3	"(iii) the formation of industry con-
4	sortia to jointly conduct testing to avoid
5	unnecessary duplication of tests, provided
6	that such consortia make data from such
7	testing available to the Administrator.
8	"(2) Implementation of alternative test-
9	ING METHODS.—To promote the development and
10	timely incorporation of new scientifically valid test
11	methods and strategies that are not based on
12	$vertebrate\ animals, the\ Administrator\ shall$
13	"(A) not later than 2 years after the date
14	of enactment of the Frank R. Lautenberg
15	Chemical Safety for the 21st Century Act, de-
16	velop a strategic plan to promote the develop-
17	ment and implementation of alternative test
18	methods and strategies to reduce, refine, or re-
19	place vertebrate animal testing and provide in-
20	formation of equivalent or better scientific qual-
21	ity and relevance for assessing risks of injury to
22	health or the environment of chemical sub-
23	stances or mixtures through, for example—
24	"(i) computational toxicology and
25	bioinformatics;

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1	"(ii) high-throughput screening meth-
2	ods;
3	"(iii) testing of categories of chemical
4	substances;
5	"(iv) tiered testing methods;
6	"(v) in vitro studies;
7	"(vi) systems biology;
8	"(vii) new or revised methods identi-
9	fied by validation bodies such as the Inter-
10	agency Coordinating Committee on the
11	Validation of Alternative Methods or the
12	Organization for Economic Co-operation
13	and Development; or
14	"(viii) industry consortia that develop
15	information submitted under this title;
16	"(B) as practicable, ensure that the stra-
17	tegic plan developed under subparagraph (A) is
18	reflected in the development of requirements for
19	testing under this section;
20	"(C) include in the strategic plan devel-
21	oped under subparagraph (A) a list, which the
22	Administrator shall update on a regular basis,
23	of particular alternative test methods or strate-
24	gies the Administrator has identified that do
25	not require new vertebrate animal testing and

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	are scientifically reliable, relevant, and capable
1	of providing information of equivalent or better
	scientific reliability and quality to that which
	would be obtained from vertebrate animal test·
	ing for specific health and environmental
	endpoints;
	"(D) provide an opportunity for public no
	tice and comment on the contents of the plan
	developed under subparagraph (A), including
	the criteria for considering scientific relevance
	and value for risk assessment purposes of the
	test methods and strategies that may be identi-
	fied pursuant to subparagraph (C);
	"(E) beginning on the date that is 5 years
	after the date of enactment of the Frank R.
	Lautenberg Chemical Safety for the 21st Cen
	tury Act, and every 5 years thereafter, submit
	to Congress a report that describes the progress
	made in implementing the plan developed under
	subparagraph (A) and goals for future alter-
	native test methods and strategies implementa-
	tion; and
	"(F) prioritize and, to the extent con-
	sistent with available resources and the Admin
	istrator's other responsibilities under this title,

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1	carry out performance assessment, validation,
2	and translational studies to accelerate the devel-
3	opment of scientifically valid test methods and
4	strategies that reduce, refine, or replace the use
5	of vertebrate animals, including minimizing du-
6	plication, in any testing under this title.".
	[Section 5 replaced with HLC 4.18 and line edits —in separate document]

7—SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

8 Section 5 of the Toxic Substances Control Act (15

9 U.S.C. 2604) is amended—

	0.5.0. 2001) is unforted
10	(1) in subsection (a)
11	(A) in paragraph (1)
12	(i) by striking "Except as provided
13	in" and inserting "(A) Except as provided
14	in subparagraph (B) of this paragraph
15	———and";
16-	(ii) by redesignating subparagraphs
17	(A) and (B) as clauses (i) and (ii), respec-
18-	tively;
19	(iii) by striking all that follows "sig-
20	nificant new use" and inserting a period;
21	————and
22	(iv) by adding at the end the fol-

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23 lowing:

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24 "(B) A person may take the actions described

25 in subparagraph (A) if—

1	"(i) such person submits to the Adminis-
2	trator, at least 90 days before such manufac-
3	ture or processing, a notice, in accordance with
4—	subsection (d), of such person's intention to
5	manufacture or process such substance and
6	such person complies with any applicable re-
7	quirement imposed under subsection (b), (e), or
8	(f); and
9	"(ii) the Administrator
10	"(I) conducts a review of the notice;
11	and
12	"(II) makes a determination under
13	subparagraph (A), (B), (C), (D), or (E) of
14	paragraph (3) and takes the actions re-
15	quired in association with that determina-
16	tion under such subparagraph."; and
17—	(B) by adding at the end the following new
18-	paragraphs:
19	"(3) REVIEW AND DETERMINATION.—Not later
20	than 90 days after receipt of a notice under para-
21	graph (1), subject to section 18, the Administrator
22	shall review such notice and determine
23	"(A) that the relevant chemical substance
24	or significant new use presents or will present
25	an unreasonable risk of injury to health or the

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1	environment, without consideration of costs or
2	other nonrisk factors, including an unreason-
3	able risk to a potentially exposed or susceptible
4	subpopulation identified as relevant by the Ad-
5	ministrator under the conditions of use, in
6	which case the Administrator shall take applica-
7	ble action under subsection (f);
8	"(B) that the relevant chemical substance
9	or significant new use is likely to present an
10	unreasonable risk of injury to health or the en-
11	vironment, without consideration of costs or
12	other nonrisk factors, including an unreason-
13	able risk to a potentially exposed or susceptible
14	subpopulation identified as relevant by the Ad-
15	ministrator under the conditions of use, in
16	which case the Administrator shall
17	"(i) by consent agreement or order,
18	prohibit or otherwise restrict the manufac-
19	ture, processing, use, distribution in com-
20	merce, or disposal (as applicable) of the
21	chemical substance, or of the chemical sub-
22	stance for a significant new use, such that
23	the Administrator determines that compli-
24	ance with such prohibition or restrictions
25	is sufficient to ensure that the chemical

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1	substance or significant new use is not
2	likely to present an unreasonable risk of
3	injury to health or the environment; and
4	"(ii) take applicable action under
5	paragraphs (4) through (8) of subsection
6	(<u>f</u>);
7	"(C) that the relevant chemical substance
8	or significant new use may present an unrea-
9	sonable risk of injury to health or the environ-
10	ment, without consideration of costs, or other
11	nonrisk factors, including an unreasonable risk
12	to a potentially exposed or susceptible sub-
13	population identified as relevant by the Admin-
14	istrator under the conditions of use, in which
15	case the Administrator shall take applicable ac-
16	tion under subsection (e);
17	"(D) that the relevant chemical substance
18	or significant new use is likely not to present an
19	unreasonable risk of injury to health or the en-
20	vironment, without consideration of costs or
21	other nonrisk factors, including an unreason-
22	able risk to a potentially exposed or susceptible
23	subpopulation identified as relevant by the Ad-
24	ministrator under the conditions of use, in
25	which case the Administrator shall publish such

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1	determination and the submitter of the notice
2	may commence manufacture of the chemical
3	substance or manufacture or processing for a
4	significant new use; or
5	"(E) that the relevant chemical substance
6	is a low-hazard substance, in which case the
7	Administrator shall publish such determination
8	and the submitter of the notice may commence
9	manufacture or processing of the chemical sub-
10	stance.
11	"(4) FAILURE TO RENDER DETERMINATION.—
12	"(A) FAILURE TO RENDER DETERMINA-
13	TION.—If the Administrator fails to make a de-
14	termination on a notice under paragraph (3) by
15	the end of the applicable review period and the
16	notice has not been withdrawn by the sub-
17	mitter, the Administrator shall refund to the
18	submitter all applicable fees charged to the sub-
19	mitter for review of the notice pursuant to sec-
20	tion 26(b)(1), and the Administrator shall not
21	be relieved of any requirement to make such de-
22	termination.
23	"(B) LIMITATIONS. (i) A refund of appli-
24	cable fees under subparagraph (A) shall not be
25	made if the Administrator certifies that the

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1	submitter has not provided information required
2	under subsection (b) or (e) or has otherwise un-
3	duly delayed the process such that the Adminis-
4_	trator is unable to render a determination with-
5_	in the applicable period of review.
6-	"(ii) A failure of the Administrator to
7_	render a decision shall not be deemed to con-
8	stitute a withdrawal of the notice.
9	"(iii) Nothing in this paragraph shall be
10-	construed as relieving the Administrator or the
11	submitter of the notice from any requirement of
12	this section.
13_	"(5) Article consideration. In promul-
14_	gating a rule under paragraph (2), the Adminis-
15	trator shall consider whether there is a likely poten-
16 —	tial for exposure to a chemical substance through an
17	article or category of articles, and if the Adminis-
18	trator finds such a likely potential, the Adminis-
19_	trator shall require notification under this section
20-	for the import or processing of a chemical substance
21	as part of the article or category of articles.";
22	(2) in subsection (b)
23_	(A) in the subsection heading, by striking
24_	"Test Data" and inserting "Information";
25_	(B) in paragraph (1)—

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F:\KML\114\EC\TSCA\2016 02.XML [Discussion Draft] 23 1 (i) in subparagraph (A)— 2 (I) by striking "test data" and 3 inserting "information"; and 4 (II) by striking "such data" and inserting "such information"; and (ii) in subparagraph (B)— (I) by striking "test data" and inserting "information"; 9 (II) by striking "subsection 10 (a)(1)(A)" and inserting "subsection 11 (a)(1)(A)(i)"; and 12 (III) by striking "subsection 13 (a)(1)(B)" and inserting "subsection 14 (a)(1)(A)(ii)"; 15 (C) in paragraph (2) (i) in subparagraph (A)— (I) by striking "test data" in 17___ clause (ii) and inserting "information"; 20 (II) by striking "shall" and in-21 serting "may"; and 22 (III) by striking "data pre-23 scribed" and inserting "information 24 prescribed"; and

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25 (ii) in subparagraph (B)—

F:\KML\114\EC\TSCA\2016 02.XML [Discussion Draft] 24 1 (I) by striking "Data" and in-2 serting "Information"; 3 (II) by striking "data" both 4 places it appears and inserting "infor-------mation"; (III) by striking "show" and inserting "shows"; (IV) by striking "subsection 9 (a)(1)(A)" in clause (i) and inserting 10 "subsection (a)(1)(A)(i)"; and 11 (V) by striking "subsection 12 (a)(1)(B)" in clause (ii) and inserting 13 "subsection (a)(1)(A)(ii)"; 14 (D) in paragraph (3)— 15 (i) by striking "Data" and inserting "Information"; and (ii) by striking "paragraph (1) or (2)" 17 and inserting "paragraph (1) or (2) of this subsection or under subsection (e)"; and 20 (E) in paragraph (4) 21 (i) in subparagraph (A)(i), by insert-22 ing ", without consideration of costs or 23 other nonrisk factors" after "health or the

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24 environment"; and

25

1	(ii) in subparagraph (C), by striking
2	", except that" and all that follows
3	through "subparagraph (A)";
4	(3) in subsection (c)—
5	(A) in the subsection heading, by inserting
6	"AND REVIEW" after "NOTICE" and
7	(B) by striking "before which" and all that
8	follows through "subsection may begin";
9	(4) in subsection (d)
10	(A) by striking "test data" in paragraph
11	(1)(B) and inserting "information";
12	(B) by striking "data" each place it ap-
13	pears in paragraph (1)(C) and paragraph (2)
14	and inserting "information";
15	(C) in paragraph (2)(B), by striking "uses
16	or intended uses of such substance" and insert-
17	ing "uses of such substance identified in the no-
18	tice and any additional uses of such substance
19	that are reasonably foreseeable by the Adminis-
20	trator"; and
21	(D) in paragraph (3)
22	(i) by striking "for which the notifica-
23	tion period prescribed by subsection (a),
24	(b), or (c)" and inserting "for which the
25	applicable review period"; and

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1	(ii) by striking "such notification pe-
2_	riod" and inserting "such period";
3_	(5) in subsection (e)(1)(A), by inserting "under
4_	subsection (a)(3)(C)" after "If the Administrator
5_	determines";
6-	(6) in subsection (f)
7_	(A) in paragraph (2), by striking "section
8-	6(d)(2)(B)" and inserting "section $6(c)(3)$ ";
9_	and
10	(B) by adding at the end the following:
11	"(4) PROHIBITION.—If the Administrator
12	makes a determination under subsection (a)(3)(A) or
13_	(B) with respect to a chemical substance or a signifi-
14	cant new use, no person may commence manufac-
15	ture of the chemical substance, or manufacture or
16-	processing of the chemical substance for a signifi-
17	cant new use, pursuant to this subsection except in
18	compliance with the restrictions specified in a rule
19_	promulgated under paragraph (2).
20-	"(5) Treatment of nonconforming uses.—
21	Not later than 90 days after taking an action under
22	paragraph (2) or (3) relating to a chemical sub-
23	stance with respect to which the Administrator has
24	made a determination under subsection (a)(3)(A) or
25_	(B), the Administrator shall consider whether to

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1	promulgate a rule pursuant to subsection (a)(2) that
2	identifies as a significant new use any manufac-
3_	turing, processing, use, distribution in commerce, or
4—	disposal of the chemical substance that does not con-
5—	form to the restrictions imposed by the order, and,
6-	as applicable, initiate such a rulemaking or publish
7_	a statement describing the reasons of the Adminis-
8-	trator for not initiating such a rulemaking.
9	"(6) SELECTING PROHIBITIONS AND RESTRIC-
10	TIONS.—In selecting among prohibitions and other
11	restrictions, relating to a chemical substance with
12	respect to which the Administrator has made a de-
13_	termination under subsection (a)(3)(A) or (B), to in-
14—	clude in an order to be issued by the Administrator
15	to meet the standard under paragraph (1), the Ad-
16-	ministrator shall consider, to the extent practicable
17	based on reasonably available information, costs and
18	other nonrisk factors, and such an order shall in-
19	clude a requirement described in section 6(a).
20	"(7) Persistent and bioaccumulative sub-
21	STANCES. For a chemical substance with respect to
22	which the Administrator has made a determination
23_	under subsection (a)(3)(A) or (B) that the Adminis-
24_	trator determines, with respect to persistence and
25_	bioaccumulation, scores high for 1 and either high or

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1	moderate for the other, pursuant to the TSCA Work
2	Plan Chemicals Methods Document published by the
3	Administrator in February 2012 (or a successor
4	scoring system), the Administrator shall, in selecting
5_	among prohibitions and other restrictions to include
6-	in an order to be issued by the Administrator to
7	meet the standard under paragraph (1), reduce the
8-	$\textcolor{red}{ \color{red} potential for exposure to the substance to the extent} \\$
9_	practicable.
10	"(8) Workplace exposures.—To the extent
11	practicable, the Administrator shall consult with the
12	Assistant Secretary of Labor for Occupational Safe-
13	ty and Health prior to adopting any prohibition or
14-	other restriction relating to a chemical substance
15	with respect to which the Administrator has made a
16 -	determination under subsection (a)(3)(A) or (B) to
17	address workplace exposures.";
18	(7) by amending subsection (g) to read as fol-
19	lows:
20	"(g) Statement on Administrator Finding.—If
21	${\color{blue} \textbf{the Administrator finds, in accordance with subsection}}$
22	(a)(3)(D), that a chemical substance or significant new
23-	use is likely not to present an unreasonable risk of injury
24	to health or the environment, then notwithstanding any
25	remaining portion of the applicable review period, the sub-

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1	mitter of the notice may commence manufacture of the
2	-chemical substance or manufacture or processing for a sig-
3_	nificant new use, and the Administrator shall make public
4	a statement of the Administrator's finding. Such a state-
5-	ment shall be submitted for publication in the Federal
6-	Register as soon as is practicable before the expiration of
7	such period. Publication of such statement in accordance
8-	with the preceding sentence is not a prerequisite to the
9_	manufacturing or processing of the substance with respect
10	to which the statement is to be published.";
11	(8) in subsection (h)—
12	(A) in paragraph (1)(A), by inserting ",
13	including an unreasonable risk to a potentially
14	exposed or susceptible subpopulation identified
15	by the Administrator for the specific uses iden-
16	tified in the application" after "health or the
17	environment";
18	(B) in paragraph (2), by striking "data"
19	each place it appears and inserting "informa-
20	tion"; and
21	(C) in paragraph (4), by striking ". A rule
22	promulgated" and all that follows through "see-
23	tion 6(e)" and inserting ", including an unrea-
24	sonable risk to a potentially exposed or suscep-

1	tible subpopulation identified by the Adminis-
2	trator under the conditions of use"; and
3_	(9) by amending subsection (i) to read as fol-
4	lows:
5_	"(i) DEFINITIONS. (1) For purposes of this section,
6-	the terms 'manufacture' and 'process' mean manufac-
7_	turing or processing for commercial purposes.
8-	"(2) For purposes of this Act, the term 'requirement'
9_	- as used in this section shall not displace any statutory or
10	-common law.
11	$\hbox{\it ```(3)} For purposes of this section, the {\it term `applicable}$
12	$\hbox{-review period' means the period starting on the date the}\\$
13	Administrator receives a notice under subsection (a)(1)
14	$- and ending on the \ date \ the \ Administrator \ makes \ a \ deter-$
15	mination under subsection (a)(3), as extended pursuant
16	to subsection (c) or (c)(1)(A).".
17	SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULA-
18	TION OF CHEMICAL SUBSTANCES AND MIX-
19	TURES.
20	Section 6 of the Toxic Substances Control Act (15 $$
21	U.S.C. 2605) is amended—
22	(1) by striking the section heading and insert
23	ing "PRIORITIZATION, RISK EVALUATION, AND
24	REGULATION OF CHEMICAL SUBSTANCES AND
2.5	MIXTURES";

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1	(2) in subsection (a)—
2	(A) by striking "finds that there is a rea
3	sonable basis to conclude that" and inserting
4	"determines in accordance with subsection
5	(b)(4)(A)";
6	(B) by inserting "and subject to section
7	18, and in accordance with subsection (c)(2),"
8	after "shall by rule";
9	(C) by striking "to protect adequately
10	against such risk using the least burdensome
11	requirements" and inserting "so that the chem-
12	ical substance no longer presents such risk";
13	(D) by inserting "or otherwise restricting"
14	after "prohibiting" in paragraph (2)(A);
15	(E) by inserting "minimum" before "warn-
16	ings" both places it appears in paragraph (3);
17	(F) by striking "and monitor or conduct
18	tests" and inserting "or monitor or conduct
19	tests pursuant to section 4" in paragraph (4);
20	and
21	(G) in paragraph (7)—
22	(i) by striking "such unreasonable
23	risk of injury" and inserting "such deter-
24	mination"; and

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1	(ii) by striking "such risk of injury"
2	and inserting "such determination";
3	(3) by amending subsection (b) to read as fol-
4	lows:
5	"(b) Risk Evaluations.—
6	"(1) Prioritization for risk evalua-
7	TIONS.—
8	"(A) Establishment of process.—Not
9	later than 1 year after the date of enactment of
10	the Frank R. Lautenberg Chemical Safety for
11	the 21st Century Act, the Administrator shall
12	establish, by rule, a risk-based screening proc-
13	ess, including criteria for designating chemical
14	substances as high priority substances for risk
15	evaluations or low-priority substances for which
16	riskevaluationsarenotwarrantedatthetime.
17	The process to designate the priority of chem-
18	ical substances shall include a consideration of
19	the hazard and exposure potential of a chemical
20	substance or a category of chemical substances
21	(including consideration of persistence and bio-
22	accumulation, potentially exposed or susceptible
23	subpopulations and storage near significant
24	sources of drinking water), the conditions of use
25	or significant changes in the conditions of use

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1	of the chemical substance, and the volume or
2	significant changes in the volume of the chem-
3	ical substance manufactured or processed.
4	"(B) Identification of priorities for
5	RISK EVALUATION.—
6	"(i) High-priority substances.—
7	The Administrator shall designate as a
8	high-priority substance a chemical sub-
9	stance that the Administrator concludes,
10	without consideration of costs or other
11	nonrisk factors, may present an unreason-
12	able risk of injury to health or the environ-
13	ment because of potential hazard and a po
14	tential route of exposure under the condi-
15	tions of use, including an unreasonable
16	$risk\ to\ a\ potentially\ exposed\ or\ susceptible$
17	subpopulation identified as relevant by the
18	Administrator.
19	"(ii) Low-priority substances.—
20	The Administrator shall designate as a
21	low-priority substance a chemical sub-
22	stance with respect to which the Adminis-
23	trator concludes, based on information suf-
24	ficient to establish, without consideration
25	of costs or other nonrisk factors, that the

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chemical substance is likely not to present
an unreasonable risk of injury to health or
the environment under the conditions of
use, including an unreasonable risk to a
potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

"(C) The Administrator shall, in the rulemaking required under paragraph (1)(A) notify the public of when the prioritization begins, and provide an opportunity for comment, for each chemical substance and ensure that the time required to make a priority designation of a chemical substance be no longer than 1 year"

"(D) "The Administrator shall, in the rulemaking required under paragraph (1)(A), provide for a process to extend the deadline under subparagraph C for up to six months in order to receive or evaluate information required to be submitted in accordance with section 4(a)(2)(B), subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the substance as high-priority substance"

"(E) The Administrator shall publish each designation of a chemical substance as a high or low priority substance along with an identification of the information, analysis, and basis used to make the designations"

8 "(2) Initial risk evaluations and subse-9 QUENT DESIGNATIONS OF HIGH AND LOW-PRIORITY 10 SUBSTANCES.— "(A) INITIAL RISK EVALUATIONS.—Not 11 later than 180 days after the date of enactment 12 of the Frank R. Lautenberg Chemical Safety 13 for the 21st Century Act, the Administrator 14 shall ensure that risk evaluations are being con-15 ducted on at least 10 chemical substances 16 (629359|5) f:\VHLC\042216\042216.242.xml

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Commented [A4]: This doesn't make sense. The rulemaking under (1)(A) is to establish the general prioritization procedures. That one rulemaking cannot notify the public of every future date on which every chemical substance will ever be prioritized under TSCA. The prioritization of a particular chemical substance is a subsequent event, and it is not a rulemaking event.

What is meant here is that EPA should, in the (1)(A) rule, impose on itself an obligation to later provide the notice and comment, according to the specified parameters.

Solution:

"under paragraph (1)(A) provide for a process whereby it must notify . . ."

$F:\ \ KML\ 114\ EC\ TSCA\ 2016_02.XML$ [Discussion Draft] 34 17 drawn from the 2014 update of the TSCA 18 Work Plan for Chemical Assessments. "(B) ADDITIONAL RISK EVALUATIONS.— 19 Not later than three and one half years after 20 21 the date of enactment of the Frank R. Lauten-22 berg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evalua-23 tions are being conducted on at least 20 high-24

priority substances and that at least 20 chem-

25

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1	ical substances have been designated as low pri-
2	ority substances, subject to the limitation that
3	at least 50 percent of all chemical substances
4	on which risk evaluations are being conducted
5	by the Administrator are drawn from the 2014
6	update of the TSCA Work Plan for Chemical
7	Assessments.
8	"(C) Continuing designations and
9	RISK EVALUATIONS.—The Administrator shall
10	continue to designate priority substances and
11	—conduct risk evaluations in accordance with this
12 13	subsection, subject to the limitation described in subparagraph (B)—until all substances drawn from the 2014 update of the TSCA Work plan for Chemical Assessments have undergone risk evaluations, and until the priority of all chemical substances have been designated, at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G)
14	"(D) Preference.—In designating high-
15	priority substances, the Administrator shall give
16	preference to—
17	"(i) chemical substances that are list-
18	ed in the 2014 update of the TSCA Work
19	Plan for Chemical Assessments as having a
20	Persistence and Bioaccumulation Score of
21	3; and
22	"(ii) chemical substances that are list-
23	ed in the 2014 update of the TSCA Work
24 f:\VHLC\042216\042216.242.xml	Plan for Chemical Assessments that are

Commented [A5]: C now addresses only prioritization, so title is overbroad

Commented [A6]: The limitation described in B relates to risk evaluations, not prioritization, so this makes less sense now that the text in lines 11-13 has been stricken and this provision addresses only prioritization.

Commented [A7]: This adds back in the awkwardness of prioritizing WP chems with a pre-determined outcome, and the impossibility of complying with the (B) limitation re proportion of PBTs once the PBTs are done.

Commented [A8]: The "and" should be dropped. As we understand this, the preceding clause ("until all substances. . . . ") delimits just the period under which the B limitation is applicable, and the following clause ("until the priority. . . . ") delimits the period during which prioritization must continue. They address different question. As written, we read this to say "The Administrator shall continue to designate high priority substances. . . and until the priority of all chemical substances has been designated . . . "

Commented [A9]: Should be "has"

Commented [A10]: This seems like unnecessary direction. The bill already requires the high priority list to be refreshed on a 1-for-1 basis as risk evaluations are completed. This seems like additional but soften direction. That observation applies to (C) generally – it is not necessary to ensure continued prioritization and creates the issues identified above.

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1	known human carcinogens and have high
2	acute and chronic toxicity.
3	ϕ "(E) Metals and metal com-
4	POUNDS.—In identifying priorities for risk eval-
5	$uation\ and\ conducting\ risk\ evaluations\ of\ met \\$
6	als and metal compounds, the Administrator
7	shall use the Framework for Metals Risk As-
8	sessment of the Office of the Science Advisor,
9	Risk Assessment Forum, and dated March
10	2007 (or a successor document), and may use
11	other applicable information consistent with the
12	best available science.¿
13	"(3) Initiation of risk evaluations; des-
14	IGNATIONS.—
15	"(A) Risk evaluation initiation.—
16	Upon designating a chemical substance as a
17	high priority substance, the Administrator shall
18	initiate a risk evaluation on the substance.
19	"(B) REVISION.—The Administrator may
20	revise the designation of a low-priority sub-
21	stance based on information made available to
22	the Administrator.
23	"(C) Ongoing designations.—The Ad-
24	ministrator shall designate at least one high-
25	priority substance upon the completion of each

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1	risk evaluation (other than risk evaluations for
2	chemical substances designated under para-
3	graph (4)(C)(ii)).
4	"(4) Risk evaluation process and dead-
5	LINES.—
6	"(A) IN GENERAL.—The Administrator
7	shall conduct risk evaluations pursuant to this
8	paragraph to determine whether a chemical
9	substance presents an unreasonable risk of in-
10	jury to health or the environment, without con-
11	sideration of costs or other nonrisk factors, in-
12	cluding an unreasonable risk to a potentially ex-
13	posed or susceptible subpopulation identified as
14	relevant to the risk evaluation by the Adminis-
15	trator, under the conditions of use.
16	"(B) Establishment of process.—Not
17	later than 1 year after the date of enactment of
18	the Frank R. Lautenberg Chemical Safety for
19	the 21st Century Act, the Administrator shall
20	establish, by rule, a process to conduct risk
21	evaluations in accordance with subparagraph
22	(A).
23	"(C) REQUIREMENT.—The Administrator
24	shall conduct and publish risk evaluations, in

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1	accordance with the rule promulgated under	
2	subparagraph (B), for a chemical substance—	
3	"(i) that has been identified under	
4	paragraph (2)(A) or designated under	
5	paragraph (1)(B)(i); and	
6	"(ii) subject to subparagraph (E),	
7	that a manufacturer of the chemical sub-	
8	stance has requested, in a form and man-	
9	ner and using the criteria prescribed by	
10	the Administrator in the rule promulgated	
11	under subparagraph (B), be subjected to a	
12	risk evaluation.	
13	"(D) Scope.—The Administrator shall, as	
14	soon as practicable and not later than 6 months	
15	after each designation of a high-priority sub-	
16	stance, publish the scope of the risk evaluation	
17	to be conducted, including the hazards, expo-	
18	sures, conditions of use, and the potentially ex-	
19	posed or susceptible subpopulations the Admin-	
20	istrator expects to consider.	
21	"(E) Limitation and criteria.—	
22	"(i) Percentage requirements.—	
23	The Administrator shall ensure that, of the number of [note: substantive edit to make RE %age work]	
24	chemical substances that undergo a risk	
25	evaluation under clause (i) of subpara-	
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1	graph (C), the percentage of chemical sub-
2	stances undergoing a risk evaluation under
3	clause (ii) of subparagraph (C) is—
4	"(I) not less than 25 percent, if
5	sufficient requests are made under
6	clause (ii) of subparagraph (C); and
7	"(II) not more than 50 percent.
8	"(ii) Requested risk evalua-
9	TIONS.—Requests for risk evaluations
10	under subparagraph (C)(ii) shall be subject
11	to the payment of fees pursuant to section
12	26(b)(3)(D), and the Administrator shall
13	not expedite or otherwise provide special
14	treatment to such risk evaluations.
15	"(iii) Preference.—In deciding
16	whether to grant requests under subpara-
17	graph (C)(ii), the Administrator shall give
18	preference to requests for risk evaluations
19	on chemical substances for which the Ad-
20	ministrator determines that restrictions
21	imposed by 1 or more States have the po-
22	tential to have a significant impact on
23	interstate commerce or health or the envi-
24	ronment.

Commented [A11]: Edit above is helpful, but "percentage" here should also be changed to "number". Otherwise EPA is being told to calculate a percentage by taking some other percentage and dividing it by the number of EPA priority chems under way, and there is no direction about how to calculate that other percentage.

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1	"(iv) Exceptions.—(I) Chemical
2	substances for which requests have been
3	granted under subparagraph (C)(ii) and
4	that are not drawn from the 2014 update
5	of the TSCA Work Plan for Chemical As-
6	sessments shall not be subject to section
7	18(b).
8	"(II) Requests for risk evaluations on
9	chemical substances which are made under
10	subparagraph (C)(ii) and that are drawn
11	from the 2014 update of the TSCA Work
12	Plan for Chemical Assessments shall be
13	granted at the discretion of the Adminis
14	trator and not be subject to clause (i)(II).
15	"(F) REQUIREMENTS.—In conducting a
16	risk evaluation under this subsection, the Ad-
17	ministrator shall—
18	"(i) integrate and assess available in
19	formation on hazards and exposures for
20	the conditions of use of the chemical sub-
21	stance, including information that is rel-
22	evant to specific risks of injury to health or
23	the environment and information on poten-
24	tially exposed or susceptible subpopulations
25	identified as relevant by the Administrator;

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1	"(ii) describe whether aggregate or
2	sentinel exposures to a chemical substance
3	under the conditions of use were consid-
4	ered, and the basis for that consideration;
5	"(iii) not consider costs or other
6	nonrisk factors;
7	"(iv) take into account, where rel-
8	evant, the likely duration, intensity, fre-
9	quency, and number of exposures under
10	the conditions of use of the chemical sub-
11	stance; and
12	"(v) describe the weight of the sci-
13	entific evidence for the identified hazard
14	${\rm and} {\rm exposure}.$
15	"(G) DEADLINES.—The Administrator—
16	"(i) shall complete a risk evaluation
17	for a chemical substance as soon as prac-
18	ticable, but not later than 3 years after the
19	date on which the Administrator initiates a-the
20	risk evaluation under subparagraph (C);
21	and
22	"(ii) may extend the deadline for a
23	risk evaluation for not more than 1 year,
24	if information relating to the chemical sub-
25	stance is required to be developed in a rule,

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1	order, or consent agreement under section
2	4 and has not yet been submitted to the Ad
3	ministrator, or if such information has
4	been submitted to the Administrator within
5	the time specified in the rule, order, or
6	consentagreementandonorafterthedate
7	that is 120 days before the expiration of
8	the deadline described in clause (i).
9	"(H) NOTICE AND COMMENT.—The Ad-
10	ministrator shall provide no less than 30 days
11	public notice and an opportunity for comment
12	on a draft risk evaluation prior to publishing a
13	final risk evaluation.";
14	(4) by amending subsection (c) to read as fol-
15	lows:
16	"(c) Promulgation of Subsection (a) Rules.—
17	"(1) Deadlines.—If the Administrator deter-
18	mines that a chemical substance presents an unrea-
19	sonable risk of injury to health or the environment
20	in accordance with subsection (b)(4)(A), the Admin-
21	istrator—
22	"(A) shall propose in the Federal Register
23	a rule under subsection (a) for the chemical
24	substance not later than 1 year after the date

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1	on which the final risk evaluation regarding the
2	chemical substance is published;
3	"(B) shall publish in the Federal Register
4	a final rule not later than 2 years after the date
5	on which the final risk evaluation regarding the
6	chemical substance is published; and
7	"(C) may extend the deadlines under this
8	paragraph for not more than two years, subject
9	to the condition that the aggregate length of ex-
10	tensions under this subparagraph and sub-
11	section (b)(4)(G)(ii) does not exceed two years,
12	and subject to the limitation that the Adminis
13	trator may not extend a deadline for the publi-
14	cation of a proposed or final rule regarding a
15	chemical substance drawn from the 2014 up $$
16	date of the TSCA Work Plan for Chemical As
17	sessments or a chemical substance that, with
18	respect to persistence and bioaccumulation
19	scores high for 1 and either high or moderate
20	for the other, pursuant to the TSCA Work Plan $$
21	Chemicals Methods Document published by the
22	Administrator in February 2012 (or a successor
23	scoring system), without adequate public jus-
24	tification that demonstrates, following a review
25	of the information reasonably available to the

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1	Administrator, that the Administrator cannot
2	complete the proposed or final rule without ad-
3	ditional information regarding the chemical
4	substance.
5	"(2) Requirements for rule.—
6	"(A) STATEMENT OF EFFECTS.—In pro-
7	posing and promulgating a rule under sub-
8	section (a) with respect to a chemical substance
9	or mixture, the Administrator shall consider
10	and publish a statement based on reasonably
11	available information with respect to—
12	"(i) the effects of the chemical sub-
13	stance or mixture on health and the mag-
14	nitude of the exposure of human beings to
15	the chemical substance or mixture as identified by the Administrator in the risk evaluation;
16	"(ii) the effects of the chemical sub-
17	stance or mixture on the environment and
18	the magnitude of the exposure of the envi-
19	ronment to such substance or mixture as identified by the Administrator in the risk evaluation;
20	"(iii) the benefits of the chemical sub-
21	stance or mixture for various uses; and
22	"(iv) the reasonably ascertainable eco-
23	nomic consequences of the rule proposed and final regulatory action and the considered alternatives, including

Commented [A12]: Our understanding is that this language was modified in response to an EPA suggestion that the text of (iv) could be better aligned with the text of II and III. However, the new text creates additional alignment issues, by using different words in (iv) than in (II) and (III) to describe the alternatives EPA must consider; and it could be read to expand the required analysis for alternatives. We understand that was not the intent. Two suggestions for addressing this

1.Retain "proposed and final regulatory action" but drop "and the considered alternatives". This approach would best ensure against unintended expansion of alternatives analysis.

2.Retain "proposed and final regulatory action" but replace "and the considered alternatives" with ", and of the one more primary alternative regulatory actions considered by the Administrator as provided in subclauses (II) and (III),"

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consideration of—

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[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 45 1 "(I) the likely effect of the rule on the national economy, small busi-2 ness, technological innovation, the en-3 vironment, and public health; 4 5 "(II) the costs and benefits of the proposed and final regulatory ac-6 7 tion and of the 1 or more primary al-8 ternative regulatory actions considered 9 by the Administrator; and "(III) the cost effectiveness of 10 the proposed regulatory action and of 11 12 the 1 or more primary alternative regulatory actions considered by the Ad-13 ministrator. 14 "(B) SELECTING REQUIREMENTS.—In se-15 16 lecting among prohibitions and other restrictions, the Administrator shall factor in, to the 17 extent practicable, the considerations under 18 19 subparagraph (A). "(C) CONSIDERATION 20 OF ALTER-21 NATIVES.—Based on the information published under subparagraph (A), in deciding whether to 22 prohibit or restrict in a manner that substan-23 tially prevents a specific use of a chemical sub-24

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stance or mixture, and in setting an appropriate

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1	transition period for such action, the Adminis
2	trator shall consider, to the extent practicable,
3	whether technically and economically feasible al-
4	ternatives that benefit health or the environ-
5	ment, compared to the use so proposed to be
6	prohibited or restricted, will be reasonably
7	available as a substitute when the proposed pro-
8	hibition or other restriction takes effect.
9	"(D) REPLACEMENT PARTS.—
10	"(i) IN GENERAL.—For complex dura
11	ble goods and complex consumer goods, the
12	Administrator shall exempt replacement
13	parts that are designed prior to the date of
14	publication in the Federal Register of the
15	rule under subsection (a), unless the Ad-
16	ministrator finds that such replacement
17	parts contribute significantly to the risk,
18	identified in a risk evaluation conducted
19	under subsection (b)(4)(A)? for the chemical sub-
20	stance or for a chemical substance con-
21	tained in a mixture, to the general popu-
22	lation or to an identified potentially ex-
23	posed or susceptible subpopulation.
24	"(ii) DEFINITIONS.—In this subpara
25	graph—
40	51 apri

Commented [A13]: (b)(4)(A) is the right citation; but there is an inconsistency in the bill about whether the formulation is "under subsection (b)(4)(A)" or "in accordance with (b)(4)(A)" or "pursuant to subsection (b)(4)(A)"

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[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 47 1 "(I) the term 'complex consumer goods' means electronic or mechanical 2 devices composed of multiple manu-3 factured components, with an in-4 5 tended useful life of 3 or more years, where the product is typically not con-6 7 sumed, destroyed, or discarded after a 8 single use, and the components of 9 which would be impracticable to redesign or replace; and 10 "(II) the term 'complex durable 11 goods' means manufactured 12 goods composed of 100 or more manufac-13 tured components, with an intended 14 useful life of 5 or more years, where 15 16 the product is typically not consumed, destroyed, or discarded after a single 17 18 use. "(E) Articles.—In selecting among pro-19 hibitions and other restrictions, the Adminis-20 21 trator shall apply such prohibitions or other re-22 strictions to an article or category of articles

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containing the chemical substance or mixture

only to the extent necessary to address the

identified risks from exposure to the chemical

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1	substance or mixture from the article or category of articles, so that the substance or
2	mixture does not present an unreasonable risk
3	of injury to health or the environment identified
4	in the risk evaluation conducted in accordance
5	with subsection (b)(4)(A).

?? Page 47 line 19 – proposal to delete second instance of "category of articles" as described as redundant – per EPA TA this is not redundant and deleting this would significantly increase the burden on the Agency.

"(3) Procedures.—When prescribing a rule 6 7 under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United 8 9 States Code (without regard to any reference in such 10 section to sections 556 and 557 of such title), and shall also-11 "(A) publish a notice of proposed rule-12 13 making stating with particularity the reason for 14 the proposed rule; "(B) allow interested persons to submit 15 16 written data, views, and arguments, and make all such submissions publicly available; 17 18 "(C) promulgate a final rule based on the 19 matter in the rulemaking record; and "(D) make and publish with the rule the 20 determination described in subsection (a)."; 21 (5) by amending subsection (d) to read as folCommented [A14]: There may be some confusion about this. We were asked by Senate staff whether there was a problem with deleting the second "or category of articles" and said (correctly) there was. HLC though deleted the entire phrase "from the article or category of articles", which we would have no concern about. Not sure if Senate staff added back in that entire phrase because they thought EPA saw it as important.

Commented [A15]: Will need to add back in some statement that subsection d is being amended.

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24 "(d) Effective Date.—

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(A) amend	paragraph (1) to read as follows:
1	"(1) IN GENERAL.—In any rule under sub-
2	section (a), the Administrator shall—
3	"(A) specify the date on which it shall take
4	effect, which date shall be as soon as prac-
5	ticable;
6	"(B) except as provided in subparagraph
7	(C), specify mandatory compliance dates for all
8	of the requirements under a rule under sub-
9	section (a), which shall be as soon as prac-
10	ticable, but not later than 5 years after the date
11	of promulgation of the rule, except in a case of
12	a use exempted under subsection (g);
13	"(C) specify mandatory compliance dates
14	for the start of ban or phase out requirements
15	under a rule under subsection (a), which shall
16	be as soon as practicable, but not later than 5
17	$years\ after\ the\ date\ of\ promulgation\ of\ the\ rule,$
18	except in the case of a use exempted under sub-
19	section(g);
20	"(D) specify mandatory compliance dates
21	for full implementation of ban or phase out re-
22	quirements under a rule under subsection (a),
23	which shall be as soon as practicable; and
24	"(E) provide for a reasonable transition

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period.

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(B) Insert a r	new paragraph (2) to read as follows:
1	"(2) Variability.—As determined by the Ad-
2	ministrator, the compliance dates established under
3	paragraph (1) may vary for different affected per-
4	sons.";
	redesignate paragraph (2) as paragraph (3) and make the lowing changes: "(i) in subparagraph (A)(i)(ii), as so redesignated— insert "without consideration of costs or other nonrisk factors" after "such effective date"; and (ii) in subparagraph (B)— (I) by striking "provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule," and inserting "in accordance with paragraph (3) of subsection (c),"; and (II) by striking "; and if such a hearing" and all that follows through" or revoke it";
5	(6) in subsection (e)(4), by striking "para-
6	graphs (2) , (3) , and (4) " and inserting "paragraph
7	(3)"; and
8	(7) by adding at the end the following new sub-
9	sections:
10	"(g) Exemptions.—
11	"(1) Criteria for exemption.—The Admin-
12	istrator may, as part of a rule promulgated under
13	subsection (a), or in a separate rule, grant an ex-
14	emption from a requirement of a subsection (a) rule
15	for a specific use of a chemical substance or mix-
16	ture, if the Administrator finds that—
17	"(A) the specific use is a critical or essen-
18	tial use for which no technically and economi-
19	cally feasible safer alternative is available, tak-
20	ing into consideration hazard and exposure;

Commented [A16]: Should be (A)(i)(I)

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F:\KML\114\EC\TSCA\2016_02.XML [Discussion Draft] 50 21 "(B) compliance with the requirement, as 22 applied with respect to the specific use, would 23 significantly disrupt the national economy, na24 tional security, or critical infrastructure; or

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1	"(C) the use of the chemical substance or
2	mixture, as compared to reasonably available al-
3	ternatives, provides a substantial benefit to
4	health, the environment, or public safety.
5	"(2) Exemption analysis and statement.—
6	In proposing an exemption under this subsection,
7	the Administrator shall analyze the need for the ex
8	emption, and shall make public the analysis and a
9	statement describing how the analysis was taken
10	into account.
11	"(3) Period of Exemption.—The Adminis-
12	trator shall establish, as part of a rule under this
13	subsection, a time limit on any exemption for a time $$
14	to be determined by the Administrator as reasonable
15	on a case-by-case basis, and, by rule, may extend,
16	modify, or eliminate an exemption if the Adminis-
17	trator determines, on the basis of reasonably avail-
18	able information and after adequate public justifica-
19	tion, the exemption warrants extension or modifica-
20	tion or is no longer necessary.
21	"(4) CONDITIONS.—As part of a rule promul-
22	gated under this subsection, the Administrator shall
23	include conditions, including reasonable record
24	keeping, monitoring, and reporting requirements, to
25	the extent that the Administrator determines the

1	conditions are necessary to protect health and the
2	environment while achieving the purposes of the ex-
3	emption.
4	"(h) CHEMICALS THAT ARE PERSISTENT, BIO-
5	ACCUMULATIVE, AND TOXIC.—
6	"(1) Expedited action.—Not later than 3
7	years after the date of enactment of the Frank R.
8	Lautenberg Chemical Safety for the 21st Century
9	Act, the Administrator shall propose rules under
10	subsection (a) with respect to chemical substances
11	identified in the 2014 update of the TSCA Work
12	Plan for Chemical Assessments—
13	"(A) that the Administrator has a reason-
14	able basis to conclude are toxic and that with
15	respect to persistence and bioaccumulation
16	score high for one and either high or moderate
17	for the other, pursuant to the TSCA Work Plan
18	Chemicals Methods Document published by the
19	Administrator in February 2012 (or a successor
20	scoring system), and are not a metal or a metal
21	compound, and for which the Administrator has
22	not completed a Work Plan Problem Formula-
23	tion, initiated a review under section 5, or en-
24	tered into a consent agreement under section 4,
25	prior to the date of enactment of the Frank R.

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1	Lautenberg Chemical Safety for the 21st Cen-
2	tury Act; and
3	"(B) exposure to which under the condi-
4	tions of use is likely to the general population
5	or to a potentially exposed or susceptible sub-
6	population identified by the Administrator, or
7	the environment, on the basis of an exposure
8	and use assessment conducted by the Adminis-
9	trator.
10	"(2) No risk evaluation required.—The
11	Administrator shall not be required to conduct risk
12	evaluations on chemical substances that are subject
13	toparagraph (1).
14	"(3) Final rule.—Not later than 18 months
15	after proposing a rule pursuant to paragraph (1),
16	the Administrator shall promulgate a final rule
17	under subsection (a).
18	"(4) Selecting restrictions.—In selecting
19	among prohibitions and other restrictions promul-
20	gated in a rule under subsection (a) pursuant to
21	paragraph (1), the Administrator shall address the
22	risks of injury to health or the environment that the
23	Administrator determines are presented by the
24	chemical substance and shall reduce exposure to the
25	substance to the extent practicable.

1	"(5) RELATIONSHIP TO SUBSECTION (b).—If,
2	at any time prior to the date that is 90 days after
3	thedateonwhichtheAdministratorproposesarule
4	under paragraph (1) with respect to a chemical sub-
5	stance, the Administrator makes a designation under
6	subsection (b)(1)(B)(i), or receives a request under
7	subsection (b)(4)(C)(ii) that meets the criteria pre-
8	scribed by the Administrator in the rule promulgated
9	under subsection (b)(4)(B), such chemical substance
10	shall not be subject to this subsection, except that
11	in selecting among prohibitions and other restric-
12	tions promulgated in a rule pursuant to subsection
13	(a), the Administrator shall both ensure that the
14	chemical substance meets the rulemaking standard
15	$undersubsection(a)andreduceexposuretothesub\cdot$
16	stance to the extent practicable.
17	"(i) Final Agency Action.—Under this section
18	and subject to section 18—
19	"(1) a determination by the Administrator
20	under subsection (b)(4)(A) that a chemical sub-
21	stance does not present an unreasonable risk of in-
22	jury to health or the environment shall be issued by
23	order and considered to be a final agency action, ef-
24	fective beginning on the date of issuance of the
25	order; and

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[Discussion Draft]

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1 "(2) a final rule promulgated under subsection (a), and including the associated determination by the 2 Admin-Istrator under that is based on a risk evaluation conducted 3 in accordance with subsection (b)(4)(A) that a chemical substance presents an unreasonable risk of in-5 jury to health or the environment, shall be considered 7 to be a final agency action, effective beginning on 8 the date of promulgation of the final rule. "(j) CHEMICAL SUBSTANCES CURRENTLY ASSESSED 9 AS LOW-HAZARD.—Not later than one year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall publish a list of not fewer than 25 chemical substances, including uses of a chemical substance identified by the Administrator, that the Administrator has reason to conclude 15 should not be high priorities for risk evaluation under this section because information demonstrates that such chemical substances do not pose a hazard to human health or 19 the environment. "(k) DEFINITION.—For the purposes of this Act, the 20 term 'requirement' as used in this section shall not dis-21 place statutory or common law.". 23 SEC. 7. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15

Commented [A17]: Looks like the comma should be retained and the "and" stricken

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25 U.S.C. 2606) is amended—

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	56
1	(1) in subsection (b)(1), by inserting "(as iden-
2	tified by the Administrator without consideration of
3	costs or other nonrisk factors)" after "from the un-
4	reasonable risk"; and
5	(2) in subsection (f), by inserting ", without
6	consideration of costs or other nonrisk factors "after
7	"widespread injury to health or the environment".
[Page 56 – 73 (belo	w)—remove all brackets]
8	SEC. 8. REPORTING AND RETENTION OF INFORMATION.
9	(a) IN GENERAL.—Section 8 of the Toxic Substances
10	${\tt ControlAct(15U.S.C.2607)isamended-\!$
11	(1) in subsection (a)—
12	ø (A) in paragraph (1) by striking "The
13	Administrator shall promulgate" and inserting
14	"Not later than 2 years after the date of enact-
15	ment of the Frank R. Lautenberg Chemical
16-	Safety for the 21st Century Act, the Adminis-
17	trator shall promulgate or revise";
18	(B) in paragraph (2), by striking the mat-
19	ter that follows subparagraph (G);
20	(C) in paragraph (3), by adding at the end
21	the following:
22	"(C) Not later than 180 days after the date of enact-
23	ment of the Frank R. Lautenberg Chemical Safety for the
24	21st Century Act, and not less frequently than once every

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25 10 years thereafter, the Administrator, after consultation

1	with the Administrator of the Small Business Administrator $\overline{\ }$
2	tion, shall—
3	"(i) review the adequacy of the standards pre-
4	scribed under subparagraph (B); and
5	"(ii) after providing public notice and an oppor-
6	tunity for comment, make a determination as to
7	whether revision of the standards is warranted.";
8	and
9	(D) by adding at the end the following:
10	¢ "(4) Contents.—The rules promulgated pur
11	suant to paragraph (1)—;
12	# "(A) may impose differing reporting and
13	recordkeeping requirements on manufacturers
14	and processors; and ¿
15	#"(B) shall include the level of detail nec
16	essary to be reported, including the manner by
17	which use and exposure information may be re-
18	ported. ¿
19	"(5) Administration.—In carrying out this
20	section, the Administrator shall, to the extent fea-
21	sible—
22	"(A) not require reporting which is unnec-
23	essary or duplicative;

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1	"(B) minimize the cost of compliance with	
2	this section and the rules issued thereunder on	
3	small manufacturers and processors; and	
4	"(C) apply any reporting obligations to	
5	those persons likely to have information rel-	
6	evant to the effective implementation of this	
7	title.	
8	"(6) Negotiated rulemaking.—(A) The Ad-	
9	ministrator shall enter into a negotiated rulemaking	
10	pursuant to subchapter III of chapter 5 of title 5,	
11	United States Code, to develop and publish, not	
12	later than 2 years ?after the date of enactment of	
13	the Frank R. Lautenberg Chemical Safety for the	
14	21st Century Act, a proposed rule providing for lim-	
15	iting reporting for any inorganic byproducts which	
16	are subsequently recycled, reused, or reprocessed, in-	
17	eluding by any other person a proposed rule providing for limiting the reporting requirements, under this subsection, of manufacturers of any inorganic byproducts, when such byproducts, whether by the byproduct manufacturer or by any other person, are subsequently recycled, reused, or reprocessed	
18	"(B) Not later than 3 and one half years after	
19	such date of enactment, the Administrator shall pub-	
20	lish a final rule resulting from such negotiated rule	
21	making."; and	
22	(2) in subsection (b), by adding at the end the	
23	following:	
24	"(3) Nomenclature:—	

Commented [A18]: "a proposed rule providing" is

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1	"(A) IN GENERAL. In carrying out para-
2	graph (1), the Administrator shall
3	"(i) maintain the use of Class 2 no-
4—	menclature in use on the date of enact-
5	ment of the Frank R. Lautenberg Chem-
6	ical Safety for the 21st Century Act;
7	"(ii) maintain the use of the Soap and
8	Detergent Association Nomenclature Sys-
9	tem, published in March 1978 by the Ad-
10-	ministrator in section 1 of addendum III
11	of the document entitled 'Candidate List of
12	Chemical Substances', and further de-
13	scribed in appendix A of volume I of the
14	1985 edition of the Toxic Substances Con-
15	trol Act Substances Inventory (EPA Docu-
16	ment No. EPA 560/7 85 002a); and
17—	"(iii) treat all chemical substances de-
18	scribed by the following category listings,
19	when manufactured as described in such
20-	appendix, as being included on the list
21	published under paragraph (1) under the
22	Chemical Abstracts Service numbers for
23	the respective categories:
24	"(I) Cement, Portland, chemi-
25	cals, CAS No. 65997–15–1.

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1	"(II) Cement, alumina, chemi-
2	cals, CAS No. 65997 16 2.
3	"(III) Glass, oxide, chemicals,
4	CAS No. 65997—17—3.
5	"(IV) Frits, chemicals, CAS No.
6	65997-18-4.
7	"(V) Steel manufacture, chemi-
8	cals, CAS No. 65997-19-5.
9	"(VI) Ceramic materials and
10	wares, chemicals, CAS No. 66402
11	68-4.
12	"(B) MULTIPLE NOMENCLATURE CONVEN-
13 TION	S
14	"(i) IN GENERAL. The Administrator
15	shall—
16	"(I) maintain the nomenclature
17	conventions for chemical substances;
18	and
19	"(II) develop new guidance
20	——that—
21	"(aa) establishes equivalency
22	between the nomenclature con-
23	ventions for chemical substances
24	on the list published under para-
25	graph (1); and

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1	"(bb) permits persons to
2	rely on the new guidance for pur-
3	poses of determining whether a
4—	chemical substance is on the list
5—	published under paragraph (1).
6	"(ii) Multiple cas numbers.—For
7	a chemical substance determined by the
8	Administrator to appear multiple times on
9	the list in paragraph (1) under different
10-	Chemical Abstracts Service numbers, the
11-	Administrator shall develop guidance rec-
12	ognizing the multiple listings as a single
13	chemical substance.
14	"(C) RELATIONSHIP TO SECTION 5.—
15_	"(i) Chemical substances de-
16-	scribed by categories. Notwith-
17—	standing subparagraph (A), a chemical
18-	substance that is described by a category
19	listed in subparagraph (A)(iii) shall be
20—	subject to section 5 if the chemical sub-
21	stance is not included as an individual
22	chemical substance on the list published
23	under paragraph (1) as of the date of en-
24-	actment of the Frank R. Lautenberg
25_	Chemical Safety for the 21st Century Act.

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1	"(ii)		HEMIC	SAL	SUI	BSTANCES
2	-GROUPED	ВУ	CAS	NUMBI	ER	Notwith-
3	standing	subpa	ragrap	h (B),	-a -	-chemical
4	substanc	e that	is not	include	ed as	s an indi-
5	-vidual ch	emica	l subst	ance or	the	list pub-
6	lished un	der pa	ıragra	ph (1) a	ıs of	the date
7	of enactn	ient o l	the F	rank R	. La	utenberg
8	Chemica	l- Safet	y for t	he 21st	Cer	ntury Act
9	shall be s	ubject	to sect	tion 5.		

- "(3) NOMENCLATURE.—
- "(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall-
- "(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;
- "(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a); and
- (iii) treat the individual members of the categories of chemical substances identified by the Administrator as statutory mixtures, as defined in Inventory descriptions established by the Administrator, as being included on the list established under paragraph (1).

"(B)

MULTIPLE NOMENCLATURE LISTINGS.—

Following a request by a manufacturer or processor to review information reasonably available tofthe Administrator that demonstrates that a chemical substance appears multiple times on the list published under paragraph (1) under different CAS numbers, the Administrator may recognize the multiple listings as a single chemical substance.

Commented [A19]: "To the," not "tofthe"

10 "(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) Rules.— 11 (629359|5)

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12	63 "(i) In general.—Not later than 1
12	(1) IN GENERAL.—INOUTAGER MAII I
13	year after the date of enactment of the
14	Frank R. Lautenberg Chemical Safety for
15	the 21st Century Act, the Administrator,
16	by rule, shall require manufacturers, and
17	may require processors, subject to the limi-
18	tations under subsection (a)(5)(A), $5(a)(1)(A)(1)$ [?] to no
19	tify the Administrator, by not later than
20	180 days after the date on which the final
21	rule is published in the Federal Register,
22	of each chemical substance on the list pub
23	lished under paragraph (1) that the manu
24	facturer or processor, as applicable, has
25	manufactured or processed for a non-

Commented [A20]: We had trouble identifying where in the bill this change should go, because the page and line numbers provided did not seem quite right. This was our best guess, but having tried it here, we note that it doesn't work. This is the provision the prevents manufacture of a new chemical without undertaking the PMN process. Since this provision (4)(A)(I) pertains only to chemicals already on the inventory, it's not clear how that reference would be relevant. So maybe we got the wrong spot.

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1	exempt commercial purpose during the 10-
2	year period ending on the day before the
3	date of enactment of the Frank R. Lauten·
4	berg Chemical Safety for the 21st Century
5	Act.
6	"(ii) ACTIVE SUBSTANCES.—The Ad-
7	ministrator shall designate chemical sub-
8	stances for which notices are received
9	under clause (i) to be active substances on
10	the list published under paragraph (1).
11	"(iii) Inactive substances.—The
12	Administrator shall designate chemical
13	substances for which no notices are re-
14	ceived under clause (i) to be inactive sub-
15	stances on the list published under para-
16	graph (1).
17	"(iv) Limitation.—No chemical sub
18	stance on the list published under para-
19	graph (1) shall be removed from such list
20	by reason of the implementation of this
21	subparagraph, or be subject to section 5 by
22	reason of a change to active status under
23	paragraph (5)(B).

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1	
2	STANCES.—In promulgating a rule under sub-
3	paragraph (A), the Administrator shall—¿
4	ø "(i) maintain the list under para-
5	graph (1), which shall include a confiden
6	tial portion and a nonconfidential portion
7	consistent with this section and section
8	14; ¿
9	ø "(ii) require any manufacturer or
10	processor of a chemical substance on the
11	confidential portion of the list published
12	under paragraph (1) that seeks to main-
13	tain an existing claim for protection
14	against disclosure of the specific chemical
15	identity of the chemical substance as con-
16	fidential pursuant to section 14 to submit
17	a notice under subparagraph (A) that in-
18	cludes such request;
19	#"(iii) require the substantiation of
20	those claims pursuant to section 14 and in
21	accordance with the review plan described
22	in subparagraph (C); and
23	#"(iv) move any active chemical sub-
24	stance for which no request was received to
25	maintain an existing claim for protection

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1	against disclosure of the specific chemical
2	identity of the chemical substance as con-
3	fidential from the confidential portion of
4	the list published under paragraph (1) to
5	the nonconfidential portion of that list. \div
6	"(C) REVIEW PLAN.—Not later than 1
7	year after the date on which the Administrator
8	compiles the initial list of active substances pur-
9	suant to subparagraph (A), the Administrator
10	shall promulgate a rule that establishes a plan
11	to review all claims to protect the specific chem-
12	ical identities of chemical substances on the
13	$confidential\ portion\ of\ the\ list\ published\ under$
14	paragraph (1) that are asserted pursuant to
15	subparagraph (B).
16	"(D) REQUIREMENTS OF REVIEW PLAN.—
17	In establishing the review plan under subpara-
18	graph (C), the Administrator shall—
19	"(i) require ϕ , at the time requested by
20	the Administrator, ¿ all manufacturers or
21	processors asserting claims under subpara-
22	graph (B) to substantiate the claim, in ac-
23	cordance with section 14, unless the manu-
24	facturer or processor has substantiated the
25	claim in a submission made to the Admin-

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1	istrator during the 5-year period ending on
2	the date of the request by the Adminis
3	trator; and
4	"(ii) in accordance with section 14—
5	"(I) review each substantiation—
6	"(aa) submitted pursuant to
7	clause (i) to determine if the
8	claim qualifies for protection
9	from disclosure; and
10	"(bb) submitted previously
11	by a manufacturer or processor
12	and relied on in lieu of the sub-
13	stantiation required pursuant to
14	clause (i), if the substantiation
15	has not been previously reviewed
16	by the Administrator, to deter-
17	mine if the claim warrants pro-
18	tection from disclosure;
19	"(II) approve, approve in part
20	and deny in part, or deny each claim;
21	and
22	"(III) except as provided in this
23	section and section 14, protect from
24	disclosure information for which the
25	Administrator approves such a claim

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1	for a period of 10 years, unless, prior
2	to the expiration of the period—
3	"(aa) the person notifies the
4	Administrator that the person is
5	withdrawing the claim, in which
6	case the Administrator shall onot
7	protect the information from dis-
8	closure: case the Administrator shall promptly make the specific chemical identity available to the public; or
9	"(bb) the Administrator oth
10	erwise becomes aware that the
11	information does not qualify for
12	protection from disclosure, in
13	which case the Administrator
14	shall take the actions described
15	in section $14(g)(2)$.
16	"(E) TIMELINE FOR COMPLETION OF RE-
17	VIEWS.—
18	"(i) IN GENERAL.—The Administrator
19	shall implement the review plan so as to
20	complete reviews of all claims specified in
21	subparagraph (C) not later than 5 years
22	after the date on which the Administrator
23	compiles the initial list of active substances
24	pursuant to subparagraph (A).
25 f:\VHLC\042216\042216.242.xml April 22, 2016 (5:11 p.m.)	"(ii) Considerations.— (629359 5)

[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 68 1 "(I) IN GENERAL.—The Admin-2 istrator may extend the deadline for completion of the reviews for not more 3 than 2 additional years, after an ade-5 quate public justification, if the Administrator determines that the exten-6 sion is necessary based on the number 7 of claims needing review and the 8 available resources. 9 "(II) ANNUAL REVIEW GOAL AND 10 RESULTS.—At the beginning of each 11 year, the Administrator shall publish 12 an annual goal for reviews and the 13 number of reviews completed in the 14 15 prior year. 16 "(5) ACTIVE AND INACTIVE SUBSTANCES.— "(A) IN GENERAL.—The Administrator 17 shall keep designations of active substances and 18 19 inactive substances on the list published under paragraph (1) current. 20 "(B) CHANGE TO ACTIVE STATUS.— 21 "(i) IN GENERAL.—Any person that 22 intends to manufacture or process for a 23 nonexempt commercial purpose a chemical 24 25 substance that is designated as an inactive

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1	substance shall notify the Administrator
2	before the date on which the inactive sub-
3	stance is manufactured or processed.
4	"(ii) Confidential chemical iden-
5	TITY.—If a person submitting a notice
6	under clause (i) for an inactive substance
7	on the confidential portion of the list pub-
8	lished under paragraph (1) seeks to main
9	tain an existing claim for protection
10	against disclosure of the specific chemical
11	identity of the inactive substance as con-
12	fidential, the person shall, consistent with
13	the requirements of section 14—
14	"(I) in the notice submitted
15	under clause (i), assert the claim; and
16	"(II) by not later than 30 days
17	after providing the notice under clause
18	(i), substantiate the claim.
19	"(iii) Active status.—On receiving
20	a notification under clause (i), the Admin-
21	istrator shall—
22	"(I) designate the applicable
23	chemical substance as an active sub-
24	stance;

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1	"(II) pursuant to section 14,
2	promptly review any claim and associ-
3	ated substantiation submitted pursu-
4	ant to clause (ii) for protection
5	against disclosure of the specific
6	chemical identity of the chemical sub-
7	stance and approve, approve in part
8	and deny in part, or deny the claim;
9	"(III) except as provided in this
10	section and section 14, protect from
11	disclosure the specific chemical iden-
12	tity of the chemical substance for
13	which the Administrator approves a
14	claim under subclause (II) for a pe
15	riod of 10 years, unless, prior to the
16	expiration of the period—
17	"(aa) the person notifies the
18	Administrator that the person is
19	withdrawing the claim, in which
20	case the Administrator shall ø not
21	protect the information from dis-
22	elosure; case the Administrator shall promptly make the specific chemical identity available to the public; or
23	"(bb) the Administrator oth
24	erwise becomes aware that the
25	information does not qualify for
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[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 71 1 protection from disclosure, 2 which case the Administrator shall take othe actions described 3 in section 14(g)(2); and 4 5 "(IV) pursuant to section 6(b), review the priority of the chemical 6 7 substance as the Administrator deter-8 mines to be necessary. "(C) CATEGORY STATUS.—The list of inac-9 tive substances shall not be considered to be a 10 category for purposes of section 26(c). 11 "(6) Interim list of active substances.— 12 13 Prior to the promulgation of the rule required under 14 paragraph (4)(A), the Administrator shall designate 15 the chemical substances reported under part 711 of title 40, Code of Federal Regulations (as in effect on 16 17 the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act), during 18 19 the reporting period that most closely preceded the 20 date of enactment of the Frank R. Lautenberg 21 Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of 22

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section 6(b).

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1	"(7) Public information.—Subject to this
2	subsection \phiand section 14\darkappa, the Administrator shall
3	make available to the public—
4	"(A) each specific chemical identity on the
5	nonconfidential portion of the list published
6	under paragraph (1) along with the Administrator's designation of the chemical substance as an active or inactive substance.
7	"(B) the øunique identifier assigned under
8	section 14,÷ accession number, generic name,
9	and, if applicable, premanufacture notice case
10	number for each chemical substance on the con-
11	fidential portion of the list published under
12	paragraph (1) for which a claim of confiden-
13	tiality was received; and
14	"(C) the specific chemical identity of any
15	active substance for which—
16	"(i) a claim for protection against dis-
17	closure of the specific chemical identity of
18	the active substance was not asserted, as
19	required under this subsection or section
20	14;
21	"(ii) all claims for protection against
22	disclosure of the specific chemical identity
23	of the active substance have been denied
24	by the Administrator; or

Commented [A21]: 1.The section already requires EPA to designate chemical substances as active and inactive. What is gained by this additional statement of the requirement? 2. Is there some reason this obligation to identify the substance as active or inactive applies only under (A), for non-confidential substances, and not under (B), for confidential substances?

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1	"(iii) the time period for protection
2	against disclosure of the specific chemical
3	identity of the active substance has ex-
4	pired.
5	"(8) LIMITATION.—No person may assert a
6	new claim under this subsection or section 14 for
7	protection from disclosure of a specific chemical
8	identity of any active or inactive substance for which
9	a notice is received under paragraph (4)(A)(i) or
10	(5)(B)(i) that is not on the confidential portion of
11	the list published under paragraph (1).
12	"(9) CERTIFICATION.—Under the rules promul-
13	gated under this subsection, manufacturers øand
14	processors, as applicable, ¿ shall be required—
15	"(A) to certify that each notice or substan-
16	tiation the manufacturer or processor submits
17	complies with the requirements of the rule, and
18	that any confidentiality claims are true and cor-
19	rect; and
20	"(B) to retain a record ødocumenting com
21	pliance with the rule and supporting confiden
22	tiality claims ¿ for a period of 5 years beginning

on the last day of the submission period.".

[Page 56·73 (above), remove all brackets]

8(b) of the

(b) MERCURY INVENTORY.—Section

25 Toxic Substances Control Act (15 U.S.C. 2607(b)) (as f:\VHLC\042216\042216.242.xml (629359|5)

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1	amended by subsection (a)) is further amended by adding
2	at the end the following:
3	"(10) MERCURY.—
4	"(A) DEFINITION OF MERCURY.—In this
5	paragraph, notwithstanding section 3(2)(B), the
6	term 'mercury' means—
7	"(i) elemental mercury; and
8	"(ii) a mercury compound.
9	"(B) Publication.—Not later than April
10	$1,2017$, and every 3 years thereafter, the Ad
11	ministrator shall carry out and publish in the
12	Federal Register an inventory of mercury sup-
13	ply, use, and trade in the United States.
14	"(C) Process.—In carrying out the inven-
15	tory under subparagraph (B), the Adminis-
16	trator shall—
17	"(i) identify any manufacturing proc-
18	esses or products that intentionally add
19	mercury; and
20	"(ii) recommend actions, including
21	proposed revisions of Federal law or regu-
22	lations, to achieve further reductions in
23	mercury use.
24	"(D) Reporting.—

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1	"(i) IN GENERAL.—To assist in the
2	preparation of the inventory under sub-
3	paragraph (B), any person who manufac
4	tures mercury or mercury added products
5	or otherwise intentionally uses mercury in
6	a manufacturing process shall make peri-
7	odic reports to the Administrator, at such
8	time and including such information as the
9	Administrator shall determine by rule pro-
10	mulgated not later than 2 years after the
11	date of enactment of this paragraph.
12	"(ii) Coordination.—To avoid dupli-
13	cation, the Administrator shall coordinate
14	the reporting under this subparagraph
15	with the Interstate Mercury Education and
16	Reduction Clearinghouse and any applica-
17	ble reporting requirements under the Solid
18	Waste Disposal Act.
19	"(iii) Exemption.—Clause (i) shall
20	not apply to a person engaged in the gen-
21	eration, handling, or management of mer-
22	cury containing waste, unless that person
23	manufactures or recovers mercury in the
24	management of that waste.".

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	[***Add back Definitions of "active" and "inactive"]	Commented [A22]: Conceptually ok
	???	
stances for whi	UBSTANCES.—The Administrator shall designate chemical sub- ch notices are received under clause (i) to be active substances on the inder paragraph (1).	
substances for	SUBSTANCES.—TheAdministrator shall designate chemical which no notices are re-ceived under clause (i) to be inactive sublist published under para-graph (1).	Commented [A23]: These provisions already appear on p 64. Perhaps the intent is to add the definitions
1	SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.	from 8(f)(1) and (2) of senate bill and offer
2	Section 9 of the Toxic Substances Control Act (15	
3	U.S.C. 2608) is amended—	
4	(1) in subsection (a)—	
5	(A) in paragraph (1)—	
6	(i) by inserting ", without consider-	
7	ation of costs or other nonrisk factors,"	
8	after "basis to conclude"; and "has reasonable basis to conclude" and inserting "determines";	Commented [A24]: Garbled. Inserts two different
9	(ii) by inserting "under the conditions	standards.
10	of use, including an unreasonable risk to a	
11	potentially exposed or susceptible sub-	
12	population identified as relevant by the Ad-	
13-	ministrator," after "health or the environ-	
14	ment": "or will present" after "presents"; and	Commented [A25]: Garbled
	(iii) by inserting "without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use" after "or the environment";	Commented [A26]: Not clear where this goes.
15	(B) in paragraph (2)—	
16	(i) in subparagraph (A), by inserting	
17	", within the time period specified by the	
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18	77 Administrator in the report," after "issues
19	an order"; and
20	(ii) in subparagraph (B), by inserting
21	"responds within the time period specified
22	by the Administrator in the report and"
23	before "initiates, within 90";
24	(C) by redesignating paragraph (3) as
25 pa	ragraph (6); and

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1	(D) by inserting after paragraph (2) the
2	following:
3	"(3) The Administrator shall take the actions de-
4	scribed in paragraph (4) if the Administrator makes a re
5	port under paragraph (1) with respect to a chemical sub-
6	stance or mixture and the agency to which the report was
7	made does not—
8	"(A) issue the order described in paragraph
9	(2)(A) within the time period specified by the Ad-
10	ministrator in the report; or
11	"(B)(i) respond under paragraph (1) within the
12	timeframe specified by the Administrator in the re-
13	port; and
14	"(ii) initiate action within $90\mathrm{days}\mathrm{of}\mathrm{publica}$
15	tion in the Federal Register of the response de-
16	scribed in clause (i).
17	"(4) If an agency to which a report is submitted
18	$under paragraph (1)\ does\ not\ take\ the\ actions\ described$
19	in subparagraph (A) or (B) of paragraph (3), the Admin-
20	istratorshall—
21	"(A) if a risk evaluation for a chemical sub-
22	stance included in the report has not been completed
23	under section 6(b), complete the risk evaluation;
24	"(B) if the Administrator has made a deter-
25	mination of unreasonable risk in accordance with

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1	section 6(b)(4)(A), initiate action under section 6(a) with
2	respect to the risk; or
3	"(C) take any action authorized or required
4	under section 7, as appropriate applicable.
5	"(5) This subsection shall not relieve the Adminis
6	trator of any obligation to complete a risk evaluation or
7	take any required action under section 6(a) or 7 to address
8	risks from the manufacture, processing, distribution in
9	commerce, use, or disposal of a chemical substance or mix-
10	ture, or any combination of those activities, that are not
11	identified in a report issued by the Administrator under
12	paragraph (1).";
13	(2) in subsection (b)—
14	(A) by striking "The Administrator shall
15	coordinate" and inserting "(1) The Adminis
16	trator shall coordinate"; and
17	(B) by adding at the end the following:
18	"(2) In making a determination under paragraph (1)
19	that it is in the public interest for the Administrator to
20	take an action under this title with respect to a chemical
21	substance or mixture rather than under another law ad-
22	ministered in whole or in part by the Administrator, the
23	Administrator shall consider, to the extent practicable based on information rea
24	sonably available to the Administrator, the relative aspect of the risks
25	and a comparison of the estimated costs and efficiencies
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- 1 of the action to be taken under this title and an action
- 2 to be taken under such other law to protect against such
- 3 risk."; and
- 4 (3) by adding at the end the following:
- 5 "(e) Exposure Information.—In addition to the
- 6 requirements of subsection (a), if the Administrator ob-
- 7 tains information related to exposures or releases of a
- 8 chemical substance or mixture that may be prevented or
- 9 reduced under another Federal law, including a law not
- 10 administered by the Administrator, the Administrator
- 11 shall make such information available to the relevant Fed-
- 12 eral agency or office of the Environmental Protection
- 13 Agency.".

Commented [A28]: We are assuming this is intended as a replacement for TSCA 12(a)(2).

Commented [A27]: This wording is improved, but it is still not clear what 'the relative aspects of the risk"

means. Relative to what?

Section 12 - Exports

• 12(a)(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator determines, without consideration of costs or other non-risk factors, that the substance, mixture, or article will present an unreasonable risk of injury to health within the United States or to the environment of the United States, under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator. The Administrator may require, under section 4, the development of new information for any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining, without consideration of costs or other non-risk factors, whether or not such substance or mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.

Commented [A29]: The beginning of the sentence says "will present".

- 14 SEC. 10. EXPORTS OF ELEMENTAL MERCURY. [CLOSED]
- 15 (a) Prohibition on Export of Certain Mercury
- 16 COMPOUNDS.—Section 12(c) of the Toxic Substances
- 17 Control Act (15 U.S.C. 2611(c)) is amended—
- 18 (1) in the subsection heading, by inserting
- "AND MERCURY COMPOUNDS" after "MERCURY";

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1	"(A) IN GENERAL.—Effective January 1,
2	2020, the export of the following mercury com-
3	pounds is prohibited:
4	"(i) Mercury (I) chloride or calomel.
5	"(ii) Mercury (II) oxide.
6	"(iii) Mercury (II) sulfate.
7	"(iv) Mercury (II) nitrate.
8	"(v) Cinnabar or mercury sulphide.
9	"(vi) Any mercury compound that the
10	Administrator adds to the list published
11	under subparagraph (B) by rule, on deter-
12	mining that exporting that mercury com-
13	pound for the purpose of regenerating ele-
14	mental mercury is technically feasible.
15	"(B) PUBLICATION.—Not later than 90
16	days after the date of enactment of the Frank
17	R. Lautenberg Chemical Safety for the 21st
18	Century Act, and as appropriate thereafter, the
19	Administrator shall publish in the Federal Reg
20	ister a list of the mercury compounds that are
21	prohibited from export under this paragraph.
22	"(C) PETITION.—Any person may petition
23	the Administrator to add a mercury compound
24	to the list published under subparagraph (B).

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1	"(D) Environmentally sound dis-
2	POSAL.—This paragraph does not prohibit the
3	export of mercury compounds on the list pub-
4	lished under subparagraph (B) to member
5	countries of the Organization for Economic Co-
6	operation and Development for environmentally
7	sound disposal, on the condition that no mer-
8	cury or mercury compounds so exported are to
9	be recovered, recycled, or reclaimed for use, or
10	directly reused, after such export.
11	"(E) REPORT.—Not later than 5 years
12	after the date of enactment of the Frank R.
13	Lautenberg Chemical Safety for the 21st Cen-
14	tury Act, the Administrator shall evaluate any
15	exports of mercury compounds on the list pub-
16	lished under subparagraph (B) for disposal that
17	occurred after such date of enactment and shall
18	submit to Congress a report that—
19	"(i) describes volumes and sources of
20	mercury compounds on the list published
21	under subparagraph (B) exported for dis-
22	posal;
23	"(ii) identifies receiving countries of
24	such exports;

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1	"(iii) describes methods of disposal
2	used after such export;
3	"(iv) identifies issues, if any, pre-
4	sented by the export of mercury com-
5	pounds on the list published under sub-
6	paragraph (B);
7	"(v) includes an evaluation of man-
8	agement options in the United States for
9	mercury compounds on the list published
10	under subparagraph (B), if any, that are
11	commercially available and comparable in
12	$cost\ and\ efficacy\ to\ methods\ being\ utilized$
13	in such receiving countries; and
14	"(vi) makes a recommendation re-
15	garding whether Congress should further
16	limit or prohibit the export of mercury
17	compounds on the list published under
18	subparagraph (B) for disposal.
19	"(F) EFFECT ON OTHER LAW.—Nothing
20	in this paragraph shall be construed to affect
21	the authority of the Administrator under the
22	Solid Waste Disposal Act (42 U.S.C. 6901 et
23	seq.).".

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1	(b) Temporary Generator Accumulation.—Sec-
2	tion5of the MercuryExportBanActof2008(42U.S.C.
3	6939f) is amended—
4	(1) in subsection (a)(2), by striking "2013" and
5	inserting "2019";
6	(2) in subsection (b)—
7	(A) in paragraph (1)—
8	(i) by redesignating subparagraphs
9	(A), (B), and (C), as clauses (i), (ii), and
10	(iii), respectively and indenting appro-
11	priately;
12	(ii) in the first sentence, by striking
13	"After consultation" and inserting the fol-
14	lowing:
15	"(A) Assessment and collection.—
16	After consultation";
17	(iii) in the second sentence, by strik-
18	ing "The amount of such fees" and insert-
19	ing the following:
20	"(B) Amount.—The amount of the fees
21	described in subparagraph (A)";
22	(iv) in subparagraph (B) (as so des-
23	ignated)—
24	(I) in clause (i) (as so redesig-
25	nated), by striking "publically avail-

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[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 84 1 able not later than October 1, 2012" and inserting "publicly available not 2 later than October 1, 2018"; 3 (II) in clause (ii) (as so redesig-4 5 nated), by striking "and"; (III) in clause (iii) (as so redesig-6 7 nated), by striking the period at the end and inserting", subject to clause 8 (iv); and"; and 9 (IV) by adding at the end the fol-10 lowing: 11 "(iv) for generators temporarily accu-12 mulating elemental mercury in a facility 13 subject to subparagraphs (B) and (D)(iv) 14 of subsection (g)(2) if the facility des-15 16 ignated in subsection (a) is not operational by January 1, 2019, shall be adjusted to 17 subtract the cost of the temporary accumu-18 19 lation during the period in which the facility designated under subsection (a) is not 20 21 operational."; and (v) by adding at the end the following: 22 23 "(C) CONVEYANCE OF TITLE AND PERMIT-TING.—If the facility designated in subsection 24

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1	(a) is not operational by January 1, 2020, the
2	Secretary—
3	"(i) shall immediately accept the con-
4	veyance of title to all elemental mercury
5	that has accumulated in facilities in ac-
6	cordance with subsection (g)(2)(D), before
7	January 1, 2020, and deliver the accumu
8	lated mercury to the facility designated
9	under subsection (a) on the date on which
10	the facility becomes operational;
11	"(ii) shall pay any applicable Federal
12	permitting costs, including the costs for
13	permits issued under section 3005(c) of
14	the Solid Waste Disposal Act (42 U.S.C.
15	6925(c)); and
16	"(iii) shall store, or pay the cost of
17	storage of, until the time at which a facil-
18	ity designated in subsection (a) is oper-
19	ational, accumulated mercury to which the
20	Secretary has title under this subpara
21	graph in a facility that has been issued a
22	permit under section 3005(c) of the Solid
23	Waste Disposal Act (42 U.S.C. 6925(c)).";
24	and

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1	(B) in paragraph (2), in the first sentence,
2	by striking "paragraph (1)(C)" and inserting
3	"paragraph (1)(B)(iii)"; and
4	(3) in subsection (g)(2)—
5	(A) in the undesignated material at the
6	end, by striking "This subparagraph" and in-
7	serting the following:
8	"(C) Subparagraph (B)";
9	(B) in subparagraph (C) (as designated by
10	subparagraph (A)), by inserting "of that sub-
11	paragraph" before the period at the end; and
12	(C) by adding at the end the following:
13	"(D) A generator producing elementa
14	mercury incidentally from the beneficiation or
15	processing of ore or related pollution control acceptable acceptable
16	tivities may accumulate the mercury produced
17	onsite that is destined for a facility designated
18	by the Secretary under subsection (a) for more
19	than 90 days without a permit issued under
20	section $3005(c)$ of the Solid Waste Disposal Act
21	(42 U.S.C. 6925(c)), and shall not be subject to
22	the storage prohibition of section 3004(j) of
23	that Act (42 U.S.C. 6924(j)), if—
24	"(i) the Secretary is unable to accept
25	the mercury at a facility designated by the

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1	Secretary under subsection (a) for reasons
2	beyond the control of the generator;
3	"(ii) the generator certifies in writing
4	to the Secretary that the generator will
5	ship the mercury to a designated facility
6	when the Secretary is able to accept the
7	mercury;
8	"(iii) the generator certifies in writing
9	to the Secretary that the generator is stor-
10	ing only mercury the generator has pro-
11	ducedorrecoveredonsiteandwillnotsell,
12	or otherwise place into commerce, the mer-
13	cury; and
14	"(iv) the generator has obtained an
15	identification number under section 262.12
16	of title 40, Code of Federal Regulations,
17	and complies with the requirements de-
18	scribed in paragraphs (1) through (4) of
19	section 262.34(a) of title 40, Code of Fed-
20	eral Regulations (as in effect on the date
21	of enactment of this subparagraph).
22	"(E) Management standards for tem-
23	PORARY STORAGE.—Not later than January 1,
24	2017, the Secretary, after consultation with the
25	Administrator of the Environmental Protection

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1	Agency and State agencies in affected States,
2	shall develop and make available guidance that
3	establishes procedures and standards for the
4	management and short-term storage of ele-
5	mental mercury at a generator covered under
6	subparagraph (D), including requirements to
7	ensure appropriate use of flasks or other suit-
8	able containers. Such procedures and standards
9	$shallbeprotectiveofhumanhealthandtheen\cdot$
10	vironment and shall ensure that the elemental
11	mercury is stored in a safe, secure, and effec-
12	tive manner. A generator may accumulate mer-
13	cury in accordance with subparagraph (D) im-
14	mediately upon enactment of this subpara
15	graph, and notwithstanding that guidance
16	called for by this paragraph has not been devel-
17	oped or made available.".
18	(c) Interim Status.—Section 5(d)(1) of the Mer-
19	cury Export Ban Act of 2008 (42 U.S.C. 6939f(d)(1)) is
20	amended—
21	(1) in the fourth sentence, by striking "in exist-
22	ence on or before January 1, 2013,"; and
23	(2) in the last sentence, by striking "January
24	1, 2015" and inserting "January 1, 2020".

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1	SEC 11	CONFIDENTIAL	INFORMATION
- 1	OPAC, II.	CONFIDENTIAL	IINTODINALION.

- 2 Section 14 of the Toxic Substances Control Act (15
- 3 U.S.C. 2613) is amended to read as follows:
- 4 "SEC. 14. CONFIDENTIAL INFORMATION.
- 5 "(a) IN GENERAL.—Except as provided in this sec-
- 6 tion, the Administrator shall not disclose information that
- 7 is exempt from disclosure pursuant to subsection (a) of
- 8 section 552 of title 5, United States Code, by reason of
- 9 subsection(b)(4) of that section—
- 10 "(1) that is reported to, or otherwise obtained
- by, the Administrator under this Act; and
- 12 "(2) for which the requirements of subsection
- 13 (c) are met.
- 14 In any proceeding under section 552(a) of title 5, United
- 15 States Code, to obtain information the disclosure of which
- 16 has been denied because of the provisions of this sub-
- 17 section, the Administrator may not rely on section
- 18 552(b)(3) of such title to sustain the Administrator's ac-
- 19 tion.
- 20 "(b) Information Not Protected From Disclo-
- 21 SURE.—

\$\phi\$the relationship among these paragraphs is not entirely clear;

- 22 "(1) MIXED CONFIDENTIAL AND NONCON-
- 23 FIDENTIAL INFORMATION. Subsection (a) does not
- 24 prohibit the disclosure of information that is not

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1—	protected from disclosure under this section on the
2	basis that such information contains information de-
3	scribed in subsection (a), subject to the condition
4—	that the Administrator shall protect from disclosure
5—	the information described in subsection (a) in dis-
6-	closing the information that is not protected from
7_	disclosure.
8	"(2 1) Information from health and safety
9	STUDIES.—Subsection (a) does not prohibit the dis-
10	closure of—
11	"(A) any health and safety study which is
12	submitted under this Act with respect to—
13	"(i) any chemical substance or mix-
14	ture which, on the date on which such
15	study is to be disclosed has been offered
16	for commercial distribution; or
17	"(ii) any chemical substance or mix-
18	ture for which testing is required under
19	section 4 or for which notification is re-
20	quired under section 5; and
21	"(B) any information reported to, or other
22	wise obtained by, the Administrator from a
23	health and safety study which relates to a
24	chemical substance or mixture described in
25	clause (i) or (ii) of subparagraph (A).

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1	This paragraph does not authorize the prelease /
2	disclosure?¿ [Senate raises question again] of any information, including formulas
3	(including molecular structures) of a chemical sub-
4	stance or mixture, that discloses processes used in
5	the manufacturing or processing of a chemical sub-
6	stance or mixture or, in the case of a mixture, the
7	portion of the mixture comprised by any of the
8	chemical substances in the mixture.
9	" $(3\ 2)$ Other information not protected
10	FROM DISCLOSURE.—Subsection (a) does not pro-
11	hibit the disclosure of—
12	"(A) a risk evaluation published under sec-
13	tion 6(b);
14	"(B) any general information describing
15	the manufacturing volumes, expressed as spe-
16	cific aggregated volumes or, if the Adminis-
17	trator determines that disclosure of specific ag-
18	gregated volumes would reveal confidential in-
19	formation, expressed in ranges; or
20	"(C) a general description of a process
21	used in the manufacture or processing and in-
22	dustrial, commercial, or consumer functions and
23	uses of a chemical substance, mixture, or article
24	containing a chemical substance or mixture, in-
25	cluding information specific to an industry or

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1	industry sector that customarily would be
2	shared with the general public or within an in-
3	dustry or industry sector.
	"(3) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Information that is protected from disclosure under this section and which is mixed with information that is not protectable from disclosure under this section does not lose its protection from disclosure notwithstanding that it is mixed with information that is not protectable from disclosure.
4	"(4) Bans and phase-outs.—
5	"(A) IN GENERAL.—If the Administrator
6	promulgates a rule pursuant to section 6(a)
7	that establishes a complete or partial ban or
8	phase out of a chemical substance or mixture,
9	the protection from disclosure of any informa-
10	tion under this section with respect to the
11	chemical substance or mixture shall be pre-
12	sumed to no longer apply, subject to subsection
13	(g)(1)(E) and subparagraphs (B) and (C) of
14	this paragraph.
15	"(B) Limitations.—
16	"(i) Critical use.—In the case of a
17	chemical substance or mixture for which a
18	specific condition of use is subject to an
19	exemption pursuant to section 6(g), if the
20	Administrator establishes a ban or phase
21	out described in subparagraph (A) with re \cdot

spect to the chemical substance or mixture,

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23	the presumption against protection under
24	such subparagraph shall only apply to in-
25	formation that relates solely to any condi-

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1	tions of use of the chemical substance or
2	mixture to which the exemption does not
3	apply.
4	"(ii) Export.—In the case of a chem
5	ical substance or mixture for which there is
6	manufacture, processing, or distribution in
7	commerce that meets the conditions of sec-
8	tion 12(a)(1), if the Administrator estab
9	lishes a ban or phase out described in sub-
10	paragraph (A) with respect to the chemical
11	substance or mixture, the presumption
12	against protection under such subpara-
13	graph shall only apply to information that
14	relates solely to any other manufacture,
15	processing, or distribution in commerce for the use or uses subject to the ban or phase out of
16	the chemical substance or mixture, unless
17	theAdministratormakesthedetermination
18	in section $12(a)(2)$.
19	"(iii) Partial bans and phase:
20	OUTS.—In the case of a chemical sub-
21	stance or mixture for which the Adminis-
22	trator establishes a partial ban or phase
23	out described in subparagraph (A) with re-
24	spect to a specific condition of use of the
25	chemical substance or mixture, the pre-

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sumption against protection under such
subparagraph shall only apply to informa-
tion that relates solely to the condition of
use of the chemical substance or mixture
for which the ban or phase out is estab-
lished.
"(C) REQUEST FOR NONDISCLOSURE.—
"(i) In GENERAL.—A manufacturer
or processor of a chemical substance or
mixture subject to a ban or phase out de-
scribed in this paragraph may submit to
the Administrator, within 30 days of re-
ceiving a notification under subsection
(g)(2)(A), a request, including documenta-
tion supporting such request, that some or
all of the information to which the notice
applies should not be disclosed or that its
disclosure should be delayed, and the Ad-
ministrator shall review the request under
subsection(g)(1)(E).
"(ii) Effect of no request or de-
NIAL.—If no request for nondisclosure or
delay is submitted to the Administrator
under this subparagraph, or the Adminis
trator denies such a request under sub-

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1	section (g)(1)(A), the Administrator shall, as practicable, promptly make the information public the information shall not
2	be protected from disclosure under this
3	section.
4	"(5) CERTAIN REQUESTS.—If a request is made
5	to the Administrator under section 552(a) of title 5,
6	United States Code, for information reported to or
7	otherwise obtained by the Administrator under this
8	Act that is not protected from disclosure under this
9	subsection, the Administrator may not deny the re-
10	quest on the basis of section 552(b)(4) of title 5,
11	United States Code.
12	"(c) Requirements for Confidentiality
13	CLAIMS.—
14	"(1) Assertion of claims.—
15	"(A) IN GENERAL.—A person seeking to
16	protect from disclosure any information that
17	person submits under this Act (including infor-
18	mation described in paragraph (2)) shall assert
19	to the Administrator a claim for protection
20	from disclosure concurrent with submission of
21	the information, in accordance with such rules
22	regarding a claim for protection from disclosure
23	as the Administrator has promulgated or may
24	promulgate pursuant to this title.

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1	"(B) INCLUSION.—An assertion of a claim
2	under subparagraph (A) shall include a state
3	ment that the person has—
4	"(i) taken reasonable measures to pro-
5	tect the confidentiality of the information;
6	"(ii) determined that the information
7	$is \ not \ required \ to \ be \ disclosed \ or \ otherwise$
8	made available to the public under any
9	other Federal law;
10	"(iii) a reasonable basis to conclude
11	that disclosure of the information is likely
12	to cause substantial harm to the competi-
13	tive position of the person; and
14	"(iv) a reasonable basis to believe that
15	the information is not readily discoverable
16	through reverse engineering.
17	"(C) Additional requirements for
18	CLAIMS REGARDING CHEMICAL IDENTITY IN-
19	FORMATION.—In the case of a claim under sub-
20	paragraph (A) for protection from disclosure of
21	a specific chemical identity, the claim shall in-
22	clude a structurally descriptive generic name for
23	the chemical substance that the Administrator
24	may disclose to the public, subject to the condi-
25	tion that such generic name shall—

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[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 97 1 "(i) be consistent with guidance developed by the Administrator under para-2 graph(4)(A); and 3 "(ii) describe the chemical structure 5 of the chemical substance as specifically as practicable while protecting those features 6 of the chemical structure— 7 8 "(I) that are claimed as confiden. tial; and 9 "(Π) the disclosure of which 10 would be likely to cause substantial 11 harm to the competitive position of 12 13 the person. 14 "(2) Information generally not subject fol-15 SUBSTANTIATION REQUIREMENTS.—The ТО 16 lowing information shall not be subject to substantiation requirements under paragraph (3): 17 "(A) Specific information describing the 18 19 processes used in manufacture or processing of a chemical substance, mixture, or article. 20 21 "(B) Marketing and sales information.

"(C) Information identifying a supplier or

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1	"(D) In the case of a mixture, details of
2	the full composition of the mixture and the re-
3	${\it spective percentages of constituents.}$
4	"(E) Specific information regarding the
5	use, function, or application of a chemical sub-
6	stance or mixture in a process, mixture, or arti-
7	cle.
8	$\hbox{``(F) Specific production} or import volumes $
9	of the manufacturer or processor.
10	"(G) Prior to the date on which a chemical
11	substance is first offered for commercial dis-
12	tribution, the specific chemical identity of the
13	chemical substance, including the chemical
14	name, molecular formula, Chemical Abstracts
15	Service number, and other information that
16	would identify the specific chemical substance,
17	if the specific chemical identity was claimed as $% \left(x\right) =\left(x\right) +\left(x\right) +\left$
18	confidential at the time it was submitted in a
19	notice under section 5.
20	"(3) Substantiation requirements.—Ex-
21	cept for information described in paragraph (2), a
22	person asserting a claim to protect information from
23	$\ disclosure\ under\ this\ section\ shall\ substantiate\ the$
24	claim, in accordance with such rules as the Adminis-

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1	trator has promulgated or may promulgate pursuant
2	to this section.
3	"(4) GUIDANCE.—The Administrator shall de-
4	velop guidance regarding—
5	"(A) the determination of structurally de-
6	scriptive generic names, in the case of claims
7	for the protection from disclosure of specific
8	chemical identity; and
9	"(B) the content and form of the state-
10	ments of need and agreements required under
11	paragraphs (4), (5), and (6) of subsection (d).
12	"(5) CERTIFICATION.—An authorized official of
13	a person described in paragraph (1)(A) shall certify
14	that the statement required to assert a claim sub-
15	mittedpursuanttoparagraph(1)(B),andanyinfor
16	mation required to substantiate a claim submitted
17	pursuant to paragraph (3), are true and correct.
18	"(d) Exceptions to Protection From Disclo-
19	SURE.—Information described in subsection (a)—
20	"(1) shall be disclosed to an officer or employee
21	of the United States—
22	"(A) in connection with the official duties
23	of that person under any Federal law for the
24	protection of health or the environment; or

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1	"(B) for a specific Federal law enforce-
2	mentpurpose;
3	"(2) shall be disclosed to a contractor of the
4	United States and employees of that contractor—
5	"(A) if, in the opinion of the Adminis-
6	trator, the disclosure is necessary for the satis-
7	factory performance by the contractor of a con-
8	tract with the United States for the perform-
9	ance of work in connection with this Act; and
10	"(B) subject to such conditions as the Ad-
11	ministrator may specify;
12	"(3) shall be disclosed if the Administrator de-
13	termines, that disclosure is necessary to protect
14	health or the environment against an unreasonable
15	risk of injury to health or the environment, without
16	consideration of costs or other nonrisk factors, in-
17	cluding an unreasonable risk to a potentially exposed
18	or susceptible subpopulation identified as relevant by
19	the Administrator under the conditions of use;
20	"(4) shall be disclosed to a State, political sub-
21	division of a State, or tribal government, on written
22	request, for the purpose of administration or en-
23	forcement of a law, if such entity has 1 or more ap-
24	plicable agreements with the Administrator that are
25	consistent with the guidance developed under sub-

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1	section (c)(4)(B) and ensure that the entity will take
2	appropriate measures, and has adequate authority,
3	to maintain the confidentiality of the information in
4	accordance with procedures comparable to the proce-
5	dures used by the Administrator to safeguard the in-
6	formation;
7	"(5) shall be disclosed to a health or environ
8	mental professional employed by a Federal or State
9	agency or tribal government or a treating physician
10	or nurse in a nonemergency situation if such person
11	provides a written statement of need and agrees to
12	sign a written confidentiality agreement with the Ad-
13	ministrator, subject to the conditions that—
14	"(A) the statement of need and confiden-
15	tiality agreement are consistent with the guid-
16	ance developed under subsection (c)(4)(B);
17	"(B) the statement of need shall be a
18	statement that the person has a reasonable
19	basis to suspect that—
20	"(i) the information is necessary for,
21	or will assist in—
22	"(I) the diagnosis or treatment of
23	1 or more individuals; or
24	"(II) responding to an environ-
25	mental release or exposure; and

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1	"(ii) 1 or more individuals being diag-
2	nosed or treated have been exposed to the
3	chemical substance or mixture concerned,
4	or an environmental release of or exposure
5	to the chemical substance or mixture con-
6	cerned has occurred; and
7	"(C) the person will not use the informa-
8	tion for any purpose other than the health or
9	environmental needs asserted in the statement
10	of need, except as otherwise may be authorized
11	by the terms of the agreement or by the person
12	who has a claim under this section with respect
13	to the information, except that nothing in this
14	title prohibits the disclosure of any such infor-
15	mation through discovery, subpoena, other
16	court order, or any other judicial process other
17	$wise \ allowed \ under \ applicable \ Federal \ or \ State$
18	law;
19	"(6) shall be disclosed in the event of an emer-
20	gency to a treating or responding physician, nurse,
21	$agent of a poison control center, public health or en \cdot$
22	vironmental official of a State, political subdivision
23	of a State, or tribal government, or first responder
24	(including any individual duly authorized by a Fed-
25	eral agency, State, political subdivision of a State, or

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1	tribal government who is trained in urgent medical
2	$care\ or\ other\ emergency\ procedures,\ including\ a\ po$
3	lice officer, firefighter, or emergency medical techni-
4	cian) if such person requests the information, sub-
5	ject to the conditions that such person shall—
6	"(A) have a reasonable basis to suspect
7	that—
8	"(i) a medical, public health, or envi-
9	ronmental emergency exists;
10	"(ii) the information is necessary for,
11	or will assist in, emergency or first aid di-
12	agnosis or treatment; or
13	"(iii) 1 or more individuals being di-
14	agnosed or treated have likely been ex-
15	posed to the chemical substance or mixture
16	concerned, or a serious environmental re-
17	lease of or exposure to the chemical sub-
18	stance or mixture concerned has occurred;
19	and
20	"(B) if requested by a person who has a
21	claim with respect to the information under this
22	section—
23	"(i) provide a written statement of
24	need and agree to sign a confidentiality

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1	agreement, as described in paragraph (5);
2	and
3	"(ii) submit to the Administrator such
4	statement of need and confidentiality
5	agreement as soon as practicable, but not
6	necessarily before the information is dis-
7	closed;
8	"(7) may be disclosed if the Administrator de-
9	termines that disclosure is relevant in a proceeding
10	under this Act, subject to the condition that the dis-
11	closure is made in such a manner as to preserve con-
12	fidentiality to the extent practicable without impair-
13	ing the proceeding; and
14	"(8) shall be disclosed if the information is re-
15	quired to be made public under any other provision
16	of Federal law.
17	"(e) Duration of Protection From Disclo-
18	SURE.—
19	"(1) IN GENERAL.—The Administrator shall
20	protect from disclosure information described in sub-
21	section (a) that meets the requirements of subsection (a) and the applicable requirements of subsection (c)—
22	"(A) in the case of information described
23	in subsection (c)(2), until such time as—
24	$\hbox{``(i) the person that asserted the claim}\\$
25	notifies the Administrator that the person

F:\KML\114\EC\TSCA\2016 02.XML [Discussion Draft] 105 1 is withdrawing the claim, in which case the information shall not be protected from disclosure under this section; or Administrator shall, as practicable, promptly make the information available to the public; or "(ii) the Administrator becomes aware 4 5 that the information does not qualify for protection from disclosure under this sec-6 7 tion, in which case the Administrator shall 8 required under take any actions subsection (f) and (g); and subsection(s) (f) and (what would happen 10 under (f)? (f) appears to not apply to (c)(2)11 information. strike? ¿ (g); and 12 "(B) \(\phi\)subject to paragraph (2), subsection 13 (f)(3), and section 8(b), ¿ ølink is needed to pre-14 vent conflicting deadlines; in the case of information other than information described in sub-15 section (c)(2)— 16 "(i) for a period of 10 years from the 17 date on which the person asserts the claim 18 with respect to the information submitted to the 19 Ad· 20 ministrator; or 21 "(ii) **ø**if applicable before the expiration of such 10-year period, ¿ since this is 22 an 'or' list and (i) has a set period, need a

rule to decide which clause applies; if applicable

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before the expiration of such 10-year period, until

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such time as—

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1	"(I) the person that asserted the
2	claim notifies the Administrator that
3	the person is withdrawing the claim,
4	in which case the information shall
5	not be protected from disclosure
6	under this section; in which case the Administrator shall, as practicable promptly make the information available to the public; or
7	"(II) the Administrator becomes
8	aware that the information does not
9	qualify for protection from disclosure
10	under this section, in which case the
11	Administrator shall take any actions
12	required under subsections (f) and
13	(g).
14	"(2) Extensions.—
15	"(A) IN GENERAL.—In the case of infor-
16	mation other than information described in sub-
17	section (c)(2), not later than the date that is 60
18	days before the expiration of the period de-
19	scribed in paragraph (1)(B)(i), the Adminis-
20	trator shall provide to the person that asserted
21	the claim a notice of the impending expiration
22	of the period.
23	"(B) Request.—
24	"(i) IN GENERAL.—Not later than the
25 f:\VHLC\042216\042216.242.xml April 22, 2016 (5:11 p.m.)	date that is 30 days before the expiration $_{\tiny{\text{(629359 5)}}}$

[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 107 1 of the period described in paragraph (1)(B)(i), a person reasserting the relevant 2 claim shall submit to the Administrator a 3 request for extension substantiating, in ac-5 cordance with subsection (c)(3), the need to extend the period. 6 "(ii) Action by administrator.— 7 Not later than the date of expiration of the 8 9 period described in paragraph (1)(B)(i), the Administrator shall, in accordance with 10 subsection(g)(1)— 11 "(I) review the request submitted 12 under clause (i); 13 "(II) make a determination re-14 garding whether the claim for which 15 16 the request was submitted continues to meet the relevant requirements of 17 this section; and 18 "(III)(aa) grant an extension of 19 10 years; or 20 21 "(bb) deny the request. "(C) NO LIMIT ON NUMBER OF EXTEN-22 23 SIONS.—There shall be no limit on the number

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of extensions granted under this paragraph, if

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1	the Administrator determines that the relevant
2	request under subparagraph (B)(i)—
3	"(i) establishes the need to extend the
4	period; and
5	"(ii) meets the requirements estab-
6	lished by the Administrator.
7	"(f) REVIEW AND RESUBSTANTIATION.—
	ois anything in this subsection intended to apply to
	(2) information?¿ [SENATE: yes, (f) does apply to (2)[2]
8	"(1) Discretion of administrator.—The
9	Administrator may require any person that has
10	claimed protection for information from disclosure
11	under this section, whether before, on, or after the
12	date of enactment of the Frank R. Lautenberg
13	Chemical Safety for the 21st Century Act, to re-
14	assert and substantiate or resubstantiate the claim
15	in accordance with this section ϕ subsection (c) / this section?
16—	♦ see below :
17	"(A) after the chemical substance is des-
18	ignated as a high-priority substance under sec-
19	tion 6(b);
20	"(B) for any chemical substance des
21	ignated as an active substance under section
22	8(b)(5)(B)(iii); or

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1	"(C) if the Administrator determines that
2	disclosure of certain information currently pro-
3	tected from disclosure would be important to
4	assist the Administrator in conducting risk
5	evaluations or promulgating rules under section
6	6.
7	"(2) REVIEW REQUIRED.—The Administrator
8	shall review a claim for protection of information
9	from disclosure under this section and require any
10	personthathasclaimedprotectionforthatinforma
11	tion, whether before, on, or after the date of enact-
12	ment of the Frank R. Lautenberg Chemical Safety
13	for the 21st Century Act, to reassert and substan-
14	tiate or resubstantiate the claim in accordance with
15	<pre>øthis section/subsection(c)?; øsee above;—</pre>
16	"(A) as necessary to determine whether
17	the information qualifies for an exemption from
18	disclosure in connection with a request for in-
19	formation received by the Administrator under
20	section 552 of title 5, United States Code;
21	"(B) if the Administrator has a reasonable
22	basis to believe that the information does not
23	qualify for protection from disclosure under this
24	section; or

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1	"(C) for any chemical substance the Ad-
2	ministrator determines under ϕ in accordance with /
3	under?; section 6(b)(4)(A) presents an unrea-
4	sonable risk of injury to health or the environ-
5	ment.
6	"(3) PERIOD OF PROTECTION.—If the Adminis-
7	trator requires a person to reassert and substantiate
8	or resubstantiate a claim under this subsection, and
9	$determines that the claim continues to meet the {\tt rel} \cdot$
10	evant requirements of this section, the Administrator
11	shall protect the information subject to the claim
12	from disclosure for a period of 10 years from the
13	date of such determination, subject to any subse-
14	quent requirement by the Administrator under this
15	subsection.
16	"(g) Duties of Administrator.—
17	"(1) Determination.—
18	"(A) IN GENERAL.—Except for claims re-
19	garding information described in subsection
20	(c)(2), the Administrator shall, subject to sub-
21	paragraph (C), not later than 90 days after the
22	receipt of a claim under subsection (c), and not
23	later than $30\mathrm{days}$ after the receipt of a request
24	for extension of a claim under subsection (e) or
25	a request under subsection (b)(4)(C), review

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1	and approve, approve in part and deny in part,
2	or deny the claim or request.
3	"(B) Reasons for Denial.—If the Ad-
4	ministrator denies or denies in part a claim or
5	request under subparagraph (A) the Adminis-
6	trator shall provide to the person that asserted
7	the claim or submitted the request a written
8	statement of the reasons for the denial or de-
9	nial in part of the claim or request.
10	"(C) Subsets.—The Administrator
11	shall—
12	$\hbox{``(i)}exceptwithrespecttoinformation$
13	described in subsection (c)(2)(G), review
14	all claims or requests under this section for
15	the protection from disclosure of the spe-
16	cific chemical identity of a chemical sub-
17	stance; and
18	"(ii) review a representative subset,
19	comprising at least $25\mathrm{percent}$, of all other
20	claims or requests for protection from dis-
21	closure under this section.
22	"(D) EFFECT OF FAILURE TO ACT.—The
23	$failure\ of\ the\ Administrator\ to\ make\ a\ decision$
24	${\tt regardingaclaimorrequestforprotectionfrom}$
25	disclosure or extension under this section shall

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1	not have the effect of denying or eliminating a
2	claim or request for protection from disclosure.
3	"(E) DETERMINATION OF REQUESTS
4	UNDER SUBSECTION (b)(4)(C).—With respect to
5	a request submitted under subsection (b)(4)(C),
6	the Administrator shall, with the objective of
7	ensuring that information relevant to the pro-
8	tection of health and the environment is dis-
9	closed to the extent practicable, determine
10	whether the documentation provided by the per-
11	sonrebutswhatshallbethepresumptionofthe
12	Administrator that the public interest in the
13	disclosure of the information outweighs the
14	public or proprietary interest in maintaining the
15	protection for all or a portion of the informa-
16	tion that the person has requested not be dis-
17	closed or for which disclosure be delayed.
18	"(2) Notification.—
19	"(A) IN GENERAL.—Except as provided in
20	subparagraph (B) and subsections (b), (d), and
21	(e), if the Administrator denies or denies in
22	part a claim or request under paragraph (1),
23	concludes, in accordance with this section, that
24	the information does not qualify for protection
25	from disclosure, intends to disclose information

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pursuant to subsection (d), or promulgates a
rule under section 6(a) establishing a ban or
phase out with respect to a chemical substance
or mixture, the Administrator shall notify, in
writing, the person that asserted the claim or
submitted the request of the intent of the Ad-
ministrator to disclose the information or not
protect the information from disclosure under
this section. The notice shall be furnished by
certified mail (return receipt requested), by per-
sonal delivery, or by other means that allows
verification of the fact and date of receipt.
"(B) Disclosure of Information.—Ex-
cept as provided in subparagraph (C), the Ad $$
$ministrator\ shall\ not\ disclose\ information\ under$
this subsection until the date that is 30 days
after the date on which the person that asserted
the claim or submitted the request receives noti-
fication under subparagraph (A).
"(C) Exceptions.—
"(i) Fifteen day notification.—
For information the Administrator intends
to disclose under subsections (d)(3), (d)(4),
(d)(5), and (j), the Administrator shall not

disclose the information until the date that

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1	is 15 days after the date on which the per-
2	son that asserted the claim or submitted
3	the request receives notification under sub-
4	paragraph (A), except that, with respect to
5	information to be disclosed under sub-
6	section (d)(3), if the Administrator deter-
7	mines that disclosure of the information is
8	necessary to protect against an imminent
9	and substantial harm to health or the envi-
10	ronment, no prior notification shall be nec-
11	essary.
12	"(ii) Notification as soon as prac-
13	TICABLE.—For information the Adminis-
14	trator intends to disclose under paragraph
15	(6) of subsection (d), the Administrator
16	shall notify the person that submitted the
17	information that the information has been
18	disclosed as soon as practicable after dis-
19	closure of the information.
20	"(iii) No notification required.—
21	Notification shall not be required—
22	"(I) for the disclosure of infor-
23	mation under paragraphs (1), (2), (7),
24	or (8) of subsection (d); or

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1	"(II) for the disclosure of infor-
2	mation for which—
3	"(aa) the Administrator has
4	provided to the person that as-
5	serted the claim a notice under
6	subsection(e)(2)(A); and
7	"(bb) such person does not
8	submit to the Administrator are-
9	quest under subsection (e)(2)(B)
10	on or before the deadline estab.
11	lished in subsection (e)(2)(B)(i).
12	"(D) Appeals.—
13	"(i) Action to restrain disclo-
14	SURE.—If a person receives a notification
15	under this paragraph and believes the in-
16	formation is protected from disclosure
17	under this section, before the date on
18	which the information is to be disclosed
19	pursuant to subparagraph (B) or (C) the
20	person may bring an action to restrain dis-
21	closure of the information in—
22	"(I) the United States district
23	court of the district in which the com-
24	plainant resides or has the principal
25	place of business; or

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1	"(II) the United States District
2	Court for the District of Columbia.
3	"(ii) No disclosure.—
4	"(I) IN GENERAL.—The Admin-
5	istrator shall not disclose information
6	that is the subject of an appeal under
7	this paragraph before the date on
8	which the applicable court rules on an
9	action under clause (i).
10	"(II) Exception.—Subclause (I)
11	shall not apply to disclosure of infor-
12	mation described under subsections
13	(d)(4) and (j).
14	"(3) Request and notification system.—
15	The Administrator, in consultation with the Director
16	of the Centers for Disease Control and Prevention,
17	shall develop a request and notification system that,
18	in a format and language that is readily accessible
19	and understandable, allows for expedient and swift
20	access to information disclosed pursuant to para-
21	graphs (5) and (6) of subsection (d).
22	"(4) Unique identifier.—The Administrator
23	shall—
24	"(A)(i) develop a system to assign a
25	unique identifier to each specific chemical iden-

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1	tity for which the Administrator approves a re-
2	quest for protection from disclosure, which shall
3	not be either the specific chemical identity or a
4	structurally descriptive generic term; and
5	"(ii) apply that identifier consistently to all
6	information relevant to the applicable chemical
7	substance;
8	"(B) annually publish and update a list of
9	chemical substances, referred to by their unique
10	identifiers, for which claims to protect the spe-
11	cific chemical identity from disclosure have been
12	approved, including the expiration date for each
13	such claim;
14	"(C) ensure that any nonconfidential infor-
15	mation received by the Administrator with re-
16	spect to a chemical substance included on the
17	list published under subparagraph (B) while the
18	specific chemical identity of the chemical sub-
19	stance is protected from disclosure under this
20	section identifies the chemical substance using
21	the unique identifier and is made public; and
22	"(D) for each claim for protection of a spe-
23	cific chemical identity that has been denied by
24	the Administrator or expired, or that has been
25	withdrawn by the person who asserted the

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1	claim, and for which the Administrator has
2	used a unique identifier assigned under this
3	paragraph to protect the specific chemical iden-
4	tity in information that the Administrator has
5	made public, clearly link the specific chemical
6	identity to the unique identifier in such infor-
7	mation to the extent practicable.
8	"(h) Criminal Penalty for Wrongful Disclo-
9	SURE.—
10	"(1) Individuals subject to penalty.—
11	"(A) IN GENERAL.—Subject to subpara-
12	graph (C) and paragraph (2), an individual de-
13	scribed in subparagraph (B) shall be fined
14	under title 18, United States Code, or impris-
15	oned for not more than 1 year, or both.
16	"(B) DESCRIPTION.—An individual re-
17	ferred to in subparagraph (A) is an individual
18	who—
19	"(i) pursuant to this section, obtained
20	possession of, or has access to, information
21	protected from disclosure under this sec-
22	tion; and
23	"(ii) knowing that the information is
24	protected from disclosure under this sec-
25	tion, willfully discloses the information in

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1	any manner to any person not entitled to
2	receive that information.
3	"(C) Exception.—This paragraph shall
4	not apply to any medical professional (including
5	an emergency medical technician or other first
6	responder) who discloses any information ob-
7	tained under paragraph (5) or (6) of subsection
8	(d) to a patient treated by the medical profes-
9	sional, or to a person authorized to make med
10	ical or health care decisions on behalf of such
11	a patient, as needed for the diagnosis or treat-
12	ment of the patient.
13	"(2) Other laws.—Section 1905 of title 18,
14	United States Code, shall not apply with respect to
15	the publishing, divulging, disclosure, or making
16	known of or making available information reported to or otherwise ob-
17	tained by the Administrator under this Act.
18	"(i) Applicability.—
19	"(1) IN GENERAL.—Except as otherwise pro-
20	vided in this section, section 8, or any other applica-
21	ble Federal law, the Administrator shall have no au
22	thority—
23	"(A) to require the substantiation or re-
24	substantiation of a claim for the protection
25	from disclosure of information reported to or

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1	otherwise obtained by the Administrator under
2	this Act prior to the date of enactment of the
3	Frank R. Lautenberg Chemical Safety for the
4	21st Century Act; or
5	"(B) to impose substantiation or re-
6	substantiation requirements, with respect to the
7	protection of information described in sub-
8	section (a), under this Act that are more exten-
9	sive than those required under this section.
10	"(2) Actions prior to promulgation of
11	RULES.—Nothing in this Act prevents the Adminis-
12	trator from reviewing, requiring substantiation or re-
13	substantiation of, or approving, approving in part, or
14	denying any claim for the protection from disclosure
15	$of information before the {\it effective}\ date of {\it such rules}$
16	applicable to those claims as the Administrator may
17	$promulgate\ after\ the\ date\ of\ enactment\ of\ the\ Frank$
18	R. Lautenberg Chemical Safety for the 21st Century
19	Act.
20	"(j) Access by Congress.—Notwithstanding any
21	limitation contained in this section or any other provision
22	of law, all information reported to or otherwise obtained
23	by the Administrator (or any representative of the Admin-
24	istrator) under this Act shall be made available, upon writ-

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1	$tenrequestofanydulyauthorizedcommitteeoftheCon\cdot$		
2	gress, to such committee.".		
3	SEC. 12. PENALTIES.		
4	Section 16 of the Toxic Substances Control Act (15 $$		
5	U.S.C. 2615) is amended—		
6	(1) in subsection $(a)(1)$, by striking "\$25,000"		
7	and inserting "\$37,500"; and		
8	(2) in subsection (b)—		
9	(A) by striking "Any person" and inserting		
10	the following:		
11	"(1) IN GENERAL.—Any person";		
12	(B) by striking "\$25,000" and inserting		
13	"\$50,000"; and		
14	(C) by adding at the end the following:		
15	"(2) Imminent danger of death or serious		
16	BODILY INJURY.—		
17	"(A) IN GENERAL.—Any person who		
18	knowingly and willfully violates any provision of		
19	section 15 or 409, and who knows at the time		
20	of the violation that the violation places an indi-		
21	vidual in imminent danger of death or serious		
22	bodily injury, shall be subject on conviction to		
23	a fine of not more than \$250,000, or imprison		
24	ment for not more than 15 years, or both.		

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[Discussion Draft]

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1	"(B) Organizations.—Notwithstanding
2	the penalties described in subparagraph (A), an
3	organization that commits a knowing violation
4	described in subparagraph (A) shall be subject
5	on conviction to a fine of not more than
6	\$1,000,000 for each violation.
7	"(C) Incorporation of corresponding
8	PROVISIONS.—Subparagraphs (B) through (F)
9	of section 113(c)(5) of the Clean Air Act (42
10	U.S.C. 7413(c)(5)(B)–(F)) shall apply to the
11	prosecution of a violation under this para-
12	graph.".
13	SEC. 13. STATE-FEDERAL RELATIONSHIP.
14	øTo be determined¿
15	SEC. 14. JUDICIAL REVIEW.
16	Section 19(a) of the Toxic Substances Control Act
17	(15 U.S.C. 2618(a)) is amended—
18	(1) in paragraph (1), by adding at the end the
19	following:
20	"(C)(i) Not later than 60 days after the publi-
21	cation of a designation under section 6(b)(1)(B)(ii),
22	any person may commence a civil action to challenge
23	the designation.
24	"(ii) The United States Court of Appeals for
25	the District of Columbia Circuit shall have exclusive

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1 2). 1
paragraph."; and
(2) by striking paragraph (3).
øSEC. 15. CITIZENS' CIVIL ACTIONS.
$Section\ 20 (b)\ of\ the\ Toxic\ Substances\ Control\ Act$
(15 U.S.C. 2619(b)) is amended—¿
$\phi(1)$ in paragraph (1)(B), by striking "or" at
the end; and ¿
$\phi(2)$ in paragraph (2), by striking the period at
the end and inserting the following: ξ ", except that
no prior notification shall be required in the case of
a civil action brought to compel a decision by the
Administrator pursuant to ϕ section $18(f)(3)(B)$; or
ϕ "(3) in the case of a civil action brought to
compel a decision by the Administrator pursuant to
øsection 18(f)(3)(B)¿, after the date that is 60 days
after the deadline specified in ϕ section
18(f)(3)(B)¿.".¿
SEC. 16. CITIZENS' PETITIONS.
Section21(b)(4)oftheToxicSubstancesControlAct
(15 U.S.C. 2620(b)(4)) is amended by striking subpara-
graph (B) and inserting the following:
"(B) DE NOVO PROCEEDING.—
"(i) IN GENERAL.—In an action under
subparagraph (A) respecting a petition to ini-

[Discussion Draft]

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1	trate a proceeding to issue a rule under section
2	4, 5, 6, or 8 or issue an order under section 4
3	or 5(e) or (f), the petitioner shall be provided
4	an opportunity to have the petition considered
5	by the court in a de novo proceeding.
6	"(ii) Demonstration.—
7	"(I) IN GENERAL.—The court in a de
8	novo proceeding under this subparagraph
9	shall order the Administrator to initiate
10	the action requested by the petitioner if
11	the petitioner demonstrates to the satisfac-
12	tion of the court by a preponderance of the
13	evidence that—
14	"(aa) in the case of a petition to
15	initiate a proceeding for the issuance
16	of a rule or order under section 4, the
17	information is needed for a purpose
18	identified in section 4(a);
19	"(bb) in the case of a petition to
20	issue an order under section 5(f), the
21	chemical substance may present an
22	unreasonable risk in accordance with
23	section 5(a)(3)(A) øclause (i) covers
24	rules under section 5 and orders under
25	section 5(e) and (f), but this only

Commented [A30]: This litany in the judicial review paragraph of sec 21 does not align with sec 21(a), unamended, which authorizes petitions only for rules under sections 4, 6 and 8 and orders under 5(e) and 6(b)(2) (the latter of which has been stricken in this version of the bill). The judicial review provision adds section 5 rules and 5(f) orders, and does not account for 6(b)(2). The most straightforward fix would probably be to simply drop the reference to 6(b)(2) in 21(a) and then have the citations in this provision match the citations in (a).

If that is done, though, one issue still remains. Section 21(a) and this provision (B)(i) allow petitions for 5(e) orders and judicial review of denials, but (B)(ii) provides no standard for review of denials of petitions for section 5(e) orders. Either 5(e) should be dropped from section 21 entirely, or a standard for judicial review should be added. There is a good rationale for dropping it (which would also be the simplest solution). Under current TSCA, presumably a citizen would petition for a sec 5(e) order, in order to block manufacture or processing. (EPA has never received such a petition as far as we know, and it would be unlikely that EPA could receive and process a petition within the section 5 review period.) However, under the revised section 5, it would more likely be the submitter who wants a 5(e) order, to enable manufacture or processing to commence, and the submitter would have a more powerful remedy than a sec 21 petition: a suit under TSCA section 20 to force EPA to perform the non-discretionary duty to take action within the review period, as required by section 5. So, the inclusion of 5(e) in section 21 seems like a vestige.

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1	speaks of orders under 5(e). Is that in-
2	tentional?¿; [SENATE: yes intentional]
3	"(cc) in the case of a petition to
4	initiate a proceeding for the issuance
5	of a rule under section 6(a), the
6	chemical substance presents an unrea-
7	sonable risk in accordance with sec-
8	tion 6(b)(4)(A); or
9	"(dd) in the case of a petition to
10	initiate a proceeding for the issuance
11	of a rule under section 8, there is a
12	reasonable basis to conclude that the
13	rule is necessary to protect health or
14	the environment or ensure that the
15	chemical substance does not present
16	an unreasonable risk of injury to
17	health or the environment, as deter-
18	mined without consideration of costs
19	or other nonrisk factors, under the
20	conditions of use, including an unrea-
21	sonable risk to a potentially exposed
22	or susceptible subpopulation identified
23	by the Administrator.
24	"(II) Deferment.—The court in a
25	de novo proceeding under this subpara-

Commented [A31]: Per comment above, section 21(a) does not provide for petitions for 5(f) rules. And, for the same reasons expressed in that comment, such a petition opportunity may not make sense.

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[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 126 graph may permit the Administrator to 1 2 defer initiating the action requested by the petitioner until such time as the court pre-3 scribes, if the court finds that-"(aa) the extent of the risk to 5 health or the environment alleged by 7 the petitioner is less than the extent of risks to health or the environment 8 9 with respect to which the Adminis-10 trator is taking action under this Act; 11 and "(bb) there are insufficient re-12 sources available to the Administrator 13 14 to take the action requested by the 15 petitioner.". 16 SEC. 17. STUDIES. Section 25 of the Toxic Substances Control Act (15 17 U.S.C. 2624) is repealed. SEC. 18. ADMINISTRATION OF THE ACT. Section 26 of the Toxic Substances Control Act (15 20 U.S.C. 2625) is amended— 21

(1) in subsection (b)(1)—

(A) by striking "of a reasonable fee";

to defray the cost of administering this Act"

(B) by striking "data under section 4 or 5

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1	and inserting "information under section 4 or a
2	notice or other information to be reviewed by
3	the Administrator under section 5, or who man-
4	ufactures or processes a chemical substance
5	that is the subject of a risk evaluation under
6	section 6(b), of a fee that is sufficient and not
7	more than reasonably necessary to defray the
8	cost related to such chemical substance of ad-
9	ministering sections 4, 5, and 6, and collecting,
10	processing, reviewing, and providing access to
11	and protecting from disclosure as appropriate
12	under section 14 information on chemical sub-
13	stances under this title, including contractor
14	costs incurred by the Administrator";
15	(C) by striking "Such rules shall not pro-
16	vide for any fee in excess of \$2,500 or, in the
17	case of a small business concern, any fee in ex-
18	cess of \$100."; and
19	(D) by striking "submit the data and the
20	cost to the Administrator of reviewing such
21	data" and inserting "pay such the fee and the cost
22	to the Administrator of carrying out the activi-
23	ties described in this paragraph";
24	(2) by adding at the end of subsection (b) the
25	following:

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1	"(3) Fund.—
2	"(A) ESTABLISHMENT.—There is established in
3	the Treasury of the United States a fund, to be
4	known as the TSCA Service Fee Fund (in this para-
5	graph referred to as the 'Fund'), consisting of such
6	amounts as are deposited in the Fund under this
7	paragraph.
8	"(B) Collection and deposit of fees.—
9	The Administrator shall collect the fees described in
10	this subsection and deposit those the fees in the Fund
11	"(C) Crediting and availability of
12	FEES.—On request by the Administrator, the Sec-
13	retary of the Treasury shall transfer from the Fund
14	to the Administrator amounts appropriated to pay
15	or recover the costs incurred by the Environmental
16	Protection Agency in carrying out the provisions of
17	this title for which the fees are collected under for use in defraying the costs of the activities described in para.
18	graph (1).
19	"(D) Use of funds by administrator.—
20	Fees authorized under this section shall be collected
21	and available for obligation only to the extent and in
22	the amount provided in advance in appropriations
23	Acts, and shall be available without fiscal year limi-
24	tation for use in defraying the costs of the activities
25	described in subsection (b)(1) paragraph (1).

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1	"(E) Accounting and auditing.—
2	"(i) ACCOUNTING.—The Administrator
3	shall biennially prepare and submit to the Com-
4	mittee on Environment and Public Works of the
5	Senate and the Committee on Energy and Com-
6	merce of the House of Representatives a report
7	that includes an accounting of the fees paid to
8	the Administrator under this paragraph and
9	amounts disbursed from the Fund for the pe-
10	riod covered by the report, as reflected by fi-
11	nancial statements provided in accordance with
12	sections 3515 and 3521 of title 31, United
13	States Code.
14	"(ii) Auditing.—
15	"(I) IN GENERAL.—For the purpose
16	of section 3515(c) of title 31, United
17	States Code, the Fund shall be considered
18	a component of a covered executive agency.
19	"(II) Components of Audit.—The
20	annual audit required in accordance with
21	sections 3515 and 3521 of title 31 , United
22	StatesCode, ofthefinancialstatementsof
23	activities carried out using amounts from
24	the Fund shall include an analysis of—

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[Discussion Draft] F:\KML\114\EC\TSCA\2016 02.XML 130 "(aa) 1 the fees collected and amounts disbursed under this sub-2 3 section; "(bb) the reasonableness of the 5 fees in place as of the date of the audit to meet current and projected 6 7 costs of administering the provisions 8 of this title for which the fees may be used; and 9 "(cc) the number of requests for 10 a risk evaluation made by manufac-11 turers under section 6(b)(4)(C)(ii). 12 "(III) FEDERAL RESPONSIBILITY.— 13 14 The Inspector General of the Environmental Protection Agency shall conduct 15 16 the annual audit described in subclause (II) and submit to the Administrator a re-17 port that describes the findings and any 18 19 recommendations of the Inspector General resulting from the audit. 20 "(4) Amount and Adjustment of Fees; Re-21 FUNDS.—In setting fees under this section, the Adminis-23 trator shall—

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1	"(A) prescribe lower fees for small business
2	concerns, after consultation with the Administrator
3	of the Small Business Administration;
4	"(B) set the fees established under paragraph
5	(1) at levels such that the fees will, in aggregate,
6	provide a sustainable source of funds to annually de-
7	fray—
8	"(i) the lower of—
9	"(I) 25 percent of the costs to the Ad-
10	ministrator of carrying out sections 4, 5,
11	and 6, and of collecting, processing, re-
12	viewing, and providing access to and pro-
13	tecting from disclosure as appropriate
14	under section 14 information on chemical
15	substances under this title, other than the
16	costs to conduct and complete risk evalua-
17	tions under section 6(b); or
18	"(II) $$25,000,000$ (subject to adjust-
19	ment pursuant to subparagraph (F)); and
20	"(ii) the full costs and the 50 percent por-
21	tion of the costs of risk evaluations specified in
22	subparagraph (D) (ii);
23	"(C) reflect an appropriate balance in the as-
24	sessment of fees between manufacturers and proc-

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1	essors, and allow the payment of fees by consortia
2	of manufacturers or processors;
3	"(D) notwithstanding subparagraph (B)—
4	"(i) except as provided in clause (ii), for chemical substances for which the
5	Administrator has granted a request from a
6	manufacturer pursuant to section
7	6(b)(4)(A)(ii), 6(b)(4)(C)(ii), establish the fee at a level suffi
8	cient to defray the full costs to the Adminis-
9	trator of conducting the risk evaluation under
10	section 6(b);
1	"(ii) for chemical substances for which the
12	Administrator has granted a request from a
13	manufacturer pursuant to section
14	6(b)(4)(A)(ii), 6(b)(4)(C)(ii), and which are included in the
15	2014 update of the TSCA Work Plan for
16	Chemical Assessments, establish the fee at a
17	level sufficient to defray 50 percent of the $rac{an-}{}$
18	nual costs to the Administrator of conducting
19	the risk evaluation under section 6(b); and
20	"(iii) fees collected pursuant to clauses (i)
21	and (ii) shall be applied by the Administrator
22	only to defray the costs described in clauses (i)
23	and (ii); apply fees collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses"

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- 24 "(E) prior to the establishment or amendment
- of any fees under paragraph (1), consult and meet

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1	with parties potentially subject to the fees or their
2	representatives, subject to the condition that no obli-
3	gation under the Federal Advisory Committee Act (5
4	U.S.C. App. or Subchapter II of Chapter 5 of title 5, United States Code) Senate: Ensures that the rulemaking will not be considered a negotiated rulemaking.] is applicable with respect to such meet.
5	ings;
6	"(F) beginning with the fiscal year that is 3
7	years after the date of enactment of the Frank R.
8	Lautenberg Chemical Safety for the 21st Century
9	Act, and every 3 years thereafter, after consultation
10	with parties potentially subject to the fees and their
11	representatives pursuant to subparagraph (E), in-
12	crease or decrease the fees established under para-
13	graph (1) as necessary to adjust for inflation and to
14	ensure that funds deposited in the Fund are suffi-
15	cient to defray—
16	"(i) approximately but not more than 25
17	percent of the annual costs to the Adminis-
18	trator of carrying out sections 4, 5, and 6, and
19	of collecting, processing, reviewing, and pro-
20	viding access to and protecting from disclosure
21	as appropriate under section 14 information on
22	chemical substances under this title, other than
23	the costs to conduct and complete risk evalua-
24	tions requested under section $6(b)(4)(A)(ii)$

Commented [A32]: Shouldn't this be III?

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6(b)(4)(C)(ii);

25 and

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1	"(ii) the full annual costs and the 50 -per-
2	cent portion of the annual costs of risk evalua-
3	tions specified in subparagraph (D); and
4	"(G) if a notice submitted under section 5 is
5	not reviewed or such a notice is withdrawn, refund
6	the fee or a portion of the fee if no substantial work
7	was performed on the notice.
8	"(5) Minimum Amount of Appropriations.—Fees
9	may not be assessed for a fiscal year under this section
10	unless the amount of appropriations for the Chemical Risk
11	Review and Reduction program project of the Environ-
12	mental Protection Agency for the fiscal year (excluding
13	the amount of any fees appropriated for the fiscal year) $$
14	are equal to or greater than the amount of appropriations
15	for that program project for fiscal year 2014.
16	"(6) TERMINATION.—The authority provided by this
17	subsection shall terminate at the conclusion of the fiscal $$
18	year that is 10 years after the date of enactment of the
19	Frank R. Lautenberg Chemical Safety for the 21st Cen-
20	tury Act , unless otherwise reauthorized or modified by
21	Congress."; and
22	(3) by adding at the end the following:
23	"(h) Scientific Standards.—In carrying out \sec
24	tions 4, 5, and 6, to the extent that the Administrator
25	makes a decision based on science, the Administrator shall

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1	$use\ scientific\ information,\ technical\ procedures,\ measures,$
2	methods, protocols, methodologies, or models, employed in
3	a manner consistent with the best available science, and
4	shall consider as applicable—
5	"(1) the extent to which the scientific informa-
6	tion, technical procedures, measures, methods, proto-
7	cols, methodologies, or models employed to generate
8	the information are reasonable for and consistent
9	with the intended use of the information;
10	"(2) the extent to which the information is rel-
11	evant for the Administrator's use in making a deci-
12	sion about a chemical substance or mixture;
13	$\hbox{``(3) the degree of clarity and completeness with}\\$
14	which the data, assumptions, methods, quality assur-
15	ance, and analyses employed to generate the infor-
16	mation are documented;
17	"(4) the extent to which the variability and un-
18	certainty in the information, or in the procedures,
19	measures, methods, protocols, methodologies, or
20	models, are evaluated and characterized; and
21	"(5) the extent of independent verification or
22	peer review of the information or of the procedures,
23	measures, methods, protocols, methodologies, or
24	models.

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1	"(i) WEIGHT OF SCIENTIFIC EVIDENCE.—The Ad-
2	ministrator shall make decisions under sections 4, 5, and
3	6 based on the weight of the scientific evidence.
4	"(j) Availability of Information.—Subject to
5	section 14, the Administrator shall make available to the
6	public—
7	"(1) all notices, determinations, findings, rules,
8	consent agreements, and orders of the Administrator
9	under this title;
10	"(2) any information required to be provided to
11	the Administrator under section 4;
12	"(3) a nontechnical summary of each risk eval-
13	uation conducted under section 6(b); and
14	"(4) a list of the studies considered by the Ad-
15	ministrator in carrying out each such risk evalua-
16	tion, along with and the results of those studies.
17	"(k) Reasonably Available Information.—In
18	carrying out sections 4, 5, and 6, the Administrator shall
19	take into consideration information relating to a chemical
20	substance or mixture, including hazard and exposure in-
21	formation, under the conditions of use, that is reasonably
22	available to the Administrator.
23	"(I) Policies, Procedures, and Guidance.—
24	"(1) Development.—Not later than 2 years
25	after the date of enactment of the Frank R. Lauten

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1	berg Chemical Safety for the 21st Century Act, the
2	Administrator shall develop any policies, procedures,
3	and guidance the Administrator determines are nec-
4	essary to carry out the amendments to this Act
5	made by the Frank R. Lautenberg Chemical Safety
6	for the 21st Century Act.
7	"(2) REVIEW.—Not later than 5 years after the
8	date of enactment of the Frank R. Lautenberg
9	Chemical Safety for the 21st Century Act, and not
10	less frequently than once every 5 years thereafter,
11	the Administrator shall—
12	"(A) review the adequacy of the policies,
13	procedures, and guidance developed under para-
14	graph (1), including with respect to animal,
15	nonanimal, and epidemiological test methods
16	and procedures for assessing and determining
17	risk under this title; and
18	"(B) revise such policies, procedures, and
19	guidance as the Administrator determines nec-
20	essary to reflect new scientific developments or
21	understandings.

"(3) Testing of Chemical Substances and Mixtures.—The policies, procedures, and guidance established under paragraph (1) applicable to testing of chemical substances and mixtures shall — "(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not

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interpret the lack of exposure information as a lack of exposure or exposure potential; and "(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations.

Commented [A33]: Should be subpopulations

- 22 "(34) Chemical substances with completed
- 23 RISK ASSESSMENTS.—With respect to a chemical
- substance listed in the 2014 update to the TSCA
- Work Plan for Chemical Assessments for which the

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1	Administrator has published a completed risk assess
2	ment prior to the date of enactment of the Frank
3	R. Lautenberg Chemical Safety for the 21st Century
4	Act, the Administrator may publish proposed and
5	final rules under section 6(a) that are consistent
6	with the scope of the completed risk assessment for
7	the chemical substance and consistent with other ap-
8	plicable requirements of section 6 as in effect before
9	such date of enactment.
10	"(45) GUIDANCE.—Not later than 1 year after
11	the date of enactment of the Frank R. Lautenberg
12	Chemical Safety for the 21st Century Act, the Ad
13	ministrator shall develop guidance to assist inter-
14	ested persons in developing and submitting draft
15	risk evaluations which shall be considered by the Ad-
16	ministrator. The guidance shall, at a minimum, ad-
17	dress the quality of the information submitted and
18	the process to be followed in developing draft risk
19	evaluations for consideration by the Administrator.

(6) NOTICE OF EXISTING INFORMATION.—

(A) IN GENERAL.—The Administrator shall, where such information is available, take notice of existing information regarding hazard and exposure published by other Federal agencies and the National Academies and incorporate the information in risk evaluations with the objective of increasing the efficiency of the risk evaluations.

(B) INCLUSION OF INFORMATION.—Existing information described in subparagraph (A) should be included to the extent practicable and where the Administrator determines the information is relevant and scientifically reliable.

Commented [A34]: Inlcuded where? (A) already provides for incorporation into risk evaluations. Also, A and B present two different standards for incorporating/including the information described in A.

20 "(m) Report to Congress.—

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F:\KML\114\EC\TSCA\2016_02.XML [Discussion Draft] 139 21 "(1) INITIAL REPORT.—Not later than 6 22 months after the date of enactment of the Frank R. 23 Lautenberg Chemical Safety for the 21st Century 24 Act, the Administrator shall submit to the Commit25 tees on Energy and Commerce and Appropriations

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1	of the House of Representatives and the Committees
2	on Environment and Public Works and Appropria
3	tions of the Senate a report containing an estimation
4	of—
5	"(A) the capacity of the Environmental
6	Protection Agency to conduct and publish risk
7	evaluations under øsubparagraphs (A)(i) and
8	(B) of section 6(b)(3) / not sure what this is
9	supposed to refer to ;, 6(b)(4)(C)(i) and(ii) and the resources nec-
10	essary to $\frac{\text{initiate}}{\text{of risk}}$ be conducting the minimum number of risk
11	evaluations required under øsection 6(b)(7)
12	subsection (b)(2) has the only 'minimum require-
13	ments' left in section 6. Is that what this should
14	refer to?; section 6(b)(2);
15	"(B) the capacity of the Environmental
16	Protection Agency to conduct and publish risk
17	evaluations under section 6(b)(4)(A)(ii), the
18	likely demand for such risk evaluations, and the
19	anticipated schedule for accommodating that
20	demand;
21	"(C) the capacity of the Environmental
22	Protection Agency to promulgate rules under
23	section 6(a) as required based on risk evalua-
24	tions conducted and published under section
25 f:\VHLC\042216\042216.242.xn April 22, 2016 (5:11 p.m.)	6(b); and (629359 5)

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1	"(D) the actual and anticipated efforts of
2	the Environmental Protection Agency to in-
3	crease the Agency's capacity to conduct and
4	publish risk evaluations under section 6(b).
5	"(2) Subsequent reports.—The Adminis
6	trator shall update and resubmit the report de-
7	scribed in paragraph (1) not less frequently than
8	once every 5 years.
9	"(n) Annual Plan.—At the beginning of each cal-
10	endar year, the Administrator shall publish an annual plan
11	that—
12	"(1) identifies the chemical substances for
13	which risk evaluations are expected to be completed
14	that year and the resources necessary for their com-
15	pletion;
16	$\hbox{``(2)} describes the status of each risk evaluation$
17	that has been initiated but not yet completed; and
18	"(3) if the schedule for completion of a risk
19	evaluation has changed, includes an updated sched-
20	ule for that risk evaluation.
21	"(o) Consultation With Science Advisory Com-
22	MITTEE ON CHEMICALS.—
23	"(1) ESTABLISHMENT.—Not later than 1 year
24	after the date of enactment of the Frank R. Lauten
25	berg Chemical Safety for the 21st Century Act, the

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Administrator shall establish an advisory committee,
to be known as the Science Advisory Committee on
Chemicals (referred to in this subsection as the
'Committee').
"(2) Purpose.—The purpose of the Committee
shall be to provide independent advice and expert
consultation, at the request of the Administrator,
with respect to the scientific and technical aspects of
issues relating to the implementation of this title.
"(3) Composition.—The Committee shall be
composed of representatives of such science, govern-
ment, labor, public health, public interest, animal
protection, industry, and other groups as the Admin-
istrator determines to be advisable, including rep-
resentatives that have specific scientific expertise in
the relationship of chemical exposures to women,
children, and other potentially exposed or susceptible
subpopulations.
"(4) Schedule.—The Administrator shall con-
$vene \ the \ Committee \ in \ accordance \ with \ such \ sched \\$
ule as the Administrator determines to be appro-
priate, but not less frequently than once every 2
years.
"(p) Prior Actions.—

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1	"(1) Rules, orders, and exemptions.—
2	Nothing in the Frank R. Lautenberg Chemical Safe
3	ty for the 21st Century Act eliminates, modifies, or
4	withdraws any rule promulgated, order issued, or ex-
5	emptionestablishedpursuanttothisActbeforethe
6	date of enactment of the Frank R. Lautenberg
7	Chemical Safety for the 21st Century Act.
8	"(2) Prior-initiated evaluations.—Nothing
9	$in \underline{the Frank R. Lautenberg Chemical Safety for the}$
10	21st Century Act this Act prevents the Administrator from
11	initiating a risk evaluation regarding a chemical sub-
12	stance, or from continuing or completing such risk
13	evaluation, prior to the effective date of the policies,
14	procedures, and guidance required to be developed
15	by the Administrator under this section or section 6 the Frank R. Lautenberg Chemical Safety for the 21st Century Act.
16	"(3) Actions completed prior to comple-
17	TION OF POLICIES, PROCEDURES, AND GUIDANCE.—
18	$Nothing in the {\color{red}FrankR.LautenbergChemicalSafe-}$
19	ty for the 21st Century Act this Act requires the Adminis
20	trator to revise or withdraw a completed risk evalua-
21	$tion, determination, or rule\ under this\ Act\ solely\ be$
22	cause the action was completed prior to the develop-
23	ment of a policy, procedure, or guidance under sub-
24	section (1), under the Frank R. Lautenberg Chemical Safety for the

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21st Century Act.".

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1	SEC. 19. STATE PROGRAMS.
2	Section 28 of the Toxic Substances Control Act (15 $$
3	U.S.C.2627) is amended by striking subsections (c) and
4	(d).
5	SEC. 20. CONFORMING AMENDMENTS.
6	(a) Table of Contents.—The table of contents in
7	section 1 of the Toxic Substances Control Act is amend-
8	ed—
9	(1) by striking the item relating to section 6
10	and inserting the following:
	"Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.";
11	(2) by striking the item relating to section 10
12	and inserting the following:
	"Sec. 10. Research, development, collection, dissemination, and utilization of information.";
13	(3) by striking the item relating to section 14
14	and inserting the following:
	"Sec. 14. Confidential information."; and
15	(4) by striking the item relating to section 25.
16	(b) Section 2.—Section 2(b)(1) of the Toxic Sub-
17	stances Control Act (15 U.S.C. 2601(b)(1)) is amended
18	by striking "data" both places it appears and inserting $$
19	"information".
20	(c) Section 3.—Section 3 of the Toxic Substances
21	${\rm ControlAct(15U.S.C.2602)isamended} -\!$

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1	(1) in paragraph (8) (as redesignated by section
2	3 of this Act), by striking "data" and inserting "in-
3	formation"; and
4	(2) in paragraph (15) (as redesignated by sec-
5	tion 3 of this Act)—
6	(A) by striking "standards" and inserting
7	"protocols and methodologies";
8	(B) by striking "test data" both places it
9	appears and inserting "information"; and
10	(C) by striking "data" each place it ap-
11	pears and inserting "information".
12	(d) Section 4.—Section 4 of the Toxic Substances
13	Control Act (15 U.S.C. 2603) is amended—
14	(1) in subsection (b)—
15	(A) in paragraph (1), by striking "rule"
16	each place it appears and inserting "rule, order,
17	or consent agreement";
18	(B) in paragraph (2)(B), by striking
19	"rules" and inserting "rules, orders, and con-
20	sent agreements"; and
21	(C) in paragraph (4)—
22	(i) by striking "rule under subsection
23	(a)" each place it appears and inserting
24	"rule, order, or consent agreement under
25	subsection (a)";

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1	(ii) by striking "repeals the rule" each
2	place it appears and inserting "repeals the
3	rule or order or modifies the consent
4	agreement to terminate the requirement";
5	and
6	(iii) by striking "repeals the applica-
7	tion of the rule" and inserting "repeals or
8	modifies the application of the rule, order,
9	or consent agreement";
10	(2) in subsection (c)—
11	(A) in paragraph (1), by striking "rule"
12	and inserting "rule or order";
13	(B) in paragraph (2)—
14	(i) in subparagraph (A), by striking
15	"a rule under subsection (a) or for which
16	data is being developed pursuant to such a
17	rule" and inserting "a rule, order, or con-
18	sent agreement under subsection (a) or for
19	which information is being developed pur-
20	suant to such a rule, order, or consent
21	agreement";
22	(ii) in subparagraph (B), by striking
23	"such rule or which is being developed pur-
24	suant to such rule" and inserting "such
25	rule, order, or consent agreement or which

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1	is being developed pursuant to such rule,
2	order, or consent agreement"; and
3	(iii) in the matter following subpara-
4	graph (B), by striking "the rule" and in-
5	serting "the rule or order";
6	(C) in paragraph (3)(B)(i), by striking
7	"rule promulgated" and inserting "rule, order,
8	or consent agreement"; and
9	(D) in paragraph (4)—
10	(i) by striking "rule promulgated"
11	each place it appears and inserting "rule,
12	order, or consent agreement";
13	(ii) by striking "such rule" each place
14	it appears and inserting "such rule, order,
15	or consent agreement"; and
16	(iii) in subparagraph (B), by striking
17	"the rule" and inserting "the rule, order,
18	or consent agreement";
19	(3) in subsection (d), by striking "rule" and in-
20	serting "rule, order, or consent agreement"; and
21	(4) in subsection (g), by striking "rule" and in-
22	serting "rule, order, or consent agreement".
23	(e) Section 5.—Section 5 of the Toxic Substances
24	Control Act (15 U.S.C. 2604) is amended—
25	(1) in subsection (b)—

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1	(A) in paragraph (1)(A)—
2	(i) by striking "rule promulgated"
3	and inserting "rule, order, or consent
4	agreement"; and
5	(ii) by striking "such rule" and insert-
6	ing "such rule, order, or consent agree-
7	ment";
8	(B) in paragraph (1)(B)—
9	(i) by striking "rule promulgated"
10	and inserting "rule or order"; and
11	(ii) by striking "the date of the sub-
12	mission in accordance with such rule" and
13	inserting "the required date of submis-
14	sion"; and
15	(C) in paragraph (2)(A)(ii), by striking
16	"rule promulgated" and inserting "rule, order,
17	or consent agreement"; and
18	(2) in subsection (d)(2)(C), by striking "rule"
19	and inserting "rule, order, or consent agreement".
20	(f) Section 7.—Section 7(a)(1) of the Toxic Sub-
21	stances Control Act (15 U.S.C. 2606(a)(1)) is amended,
22	in the matter following subparagraph (C), by striking "a $$
23	$rule\ under\ section\ 4,\ 5,\ 6,\ or\ title\ IV\ or\ an\ order\ under$
24	section 5 or title IV" and inserting "\$\phi\$a determination
25	under section 5 or 6.2 a rule under section 4.5. or 6 or

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1	title IV, an order under section 4 or 5 or title IV or 6(i), or a
2	consent agreement under section 4". ødoes this need to
3	pull in 6(i) orders?¿YES 6(1)
4	(g) Section 8.—Section 8(a) of the Toxic Sub-
5	stances Control Act (15 U.S.C. 2607(a)) is amended—
6	(1) in paragraph (2)(E), by striking "data" and
7	inserting "information"; and
8	(2) in paragraph (3)(A)(ii)(I), by striking "or
9	an order in effect under section 5(e)" and inserting
10	", an order in effect under section 4 or 5(e), or a
11	consent agreement under section 4". ødoes this need
12	to pull in 6(i) orders?¿ NO 6(i)
13	(h) Section 9.—Section 9 of the Toxic Substances
14	Control Act (15 U.S.C. 2608) is amended—
15	$\phi(1)$ in subsection (a), by striking "section 6"
16	each place it appears and inserting "section 6(a)";
17	and¿
18	(2) in subsection (d), by striking "Health, Edu-
19	cation, and Welfare" and inserting "Health and
20	Human Services".
21	(i) Section 10.—Section 10 of the Toxic Substances
22	Control Act (15 U.S.C. 2609) is amended—
23	(1) in the section heading, by striking "DATA"
24	and inserting "INFORMATION";

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1	(2) by striking "Health, Education, and Wel-
2	fare" each place it appears and inserting "Health
3	and Human Services";
4	(3) in subsection (b)—
5	(A) in the subsection heading, by striking
6	"Data" and inserting "Information";
7	(B) by striking "data" and inserting "in-
8	formation" in paragraph (1);
9	(C) by striking "data" and inserting "in-
10	formation" in paragraph (2)(A); and
11	(D) by striking "a data" and inserting "an
12	information" in paragraph (2)(B); and
13	(4) in subsection (g), by striking "data" and in-
14	serting "information".
15	(j) Section 11.—Section 11(b)(2) of the Toxic Sub-
16	stances Control Act (15 U.S.C. 2610(b)(2)) is amended—
17	(1) by striking "data" each place it appears in subparagraph (E)
18	and inserting "information"; and
19	(2) in subparagraph (E), by striking "rule pro-
20	mulgated" and inserting "rule promulgated, order
21	issued, or consent agreement entered into".
22	(k) Section 12.—Section 12(b)(1) of the Toxic Sub-
23	stances Control Act (15 U.S.C. 2611(b)(1)) is amended
24	by striking "data" both places it appears and inserting
25	"information".

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1	(l) Section 15.—Section 15(1) of the Toxic Sub-		
2	stances Control Act (15 U.S.C. 2614(1)) is amended by		
3	striking "(A) any rule" and all that follows through "or		
4	(D)" and inserting "any requirement of this title or any		
5	rule promulgated, order issued, or consent agreement en		
6	tered into under this title, or".		
7	(m) Section 19.—Section 19 of the Toxic Sub-		
8	stancesControlAct (15U.S.C.2618)isamended —		
9	(1) in subsection (a)—		
10	(A) in paragraph (1)(A)—		
11	(i) by striking "Not later than 60		
12	days after the date of the promulgation of		
13	a rule under section $4(a)$, $5(a)(2)$, $5(b)(4)$,		
14	6(a), 6(e), or 8, or under title II or IV"		
15	and inserting "Except as otherwise pro-		
16	vided in this title, not later than 60 days		
17	after the date on which a rule is promul-		
18	gated under this title, title II, or title IV,		
19	or the date on which an order is issued under section 4 or 6(i)(1),";		
20	(ii) by striking "such rule" and insert-		
21	ing "such rule or order"; and		
22	(iii) by striking "such a rule" and in-		
23	serting "such a rule or order";		
24	(B) in paragraph (1)(B)—		

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1	(i) by striking "Courts" and inserting
2	$\hbox{``Except as otherwise provided in this title,}\\$
3	courts"; and
4	(ii) by striking "subparagraph (A) or
5	(B) of section 6(b)(1)" and inserting "this
6	title, other than an order under section 4
7	or 6(i)(1),"; and
8	(C) in paragraph (2), by striking "rule-
9	making record" and inserting "record"; and
10	(2) in subsection (b)—
11	(A) by striking "review a rule" and insert
12	ing "review a rule, or an order under section 4
13	or 6(i)(1),";
14	(B) by striking "such rule" and inserting
15	"such rule or order";
16	(C) by striking "the rule" and inserting
17	"the rule or order";
18	(D) by striking "new rule" each place it
19	appears and inserting "new rule or order"; and
20	(E) by striking "modified rule" and insert
21	ing "modified rule or order"; and
22	(3) in subsection (c)—
23	(A) in paragraph (1)—
24	(i) in subparagraph (A)—

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1	(I) by striking "a rule" and in-
2	serting "a rule or order"; and
3	(II) by striking "such rule" and
4	inserting "such rule or order";
5	(ii) in subparagraph (B)—
6	(I) in the matter preceding clause
7	(i), by striking "a rule" and inserting
8	"a rule or order";
9	(II) by amending clause (i) to
10	read as follows:
11	"(i) in the case of review of—
12	"(I) a rule under section 4(a), 5(b)(4),
13	6(a) (including review of the associated deter-
14	mination under section $6(b)(4)(A)$), or $6(e)$, the
15	standard for review prescribed by paragraph
16	(2)(E) of such section 706 shall not apply and
17	the court shall hold unlawful and set aside such
18	rule if the court finds that the rule is not sup-
19	ported by substantial evidence in the rule
20	making record taken as a whole; and
21	"(II) an order under section 4 or 6(i)(1),
22	the standard for review prescribed by para-
23	graph (2)(E) of such section 706 shall not
24	apply and the court shall hold unlawful and set
25	aside such order if the court finds that the

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1	order is not supported by substantial evidence
2	in the record taken as a whole; and"; and
3	(III) by striking clauses (ii) and
4	(iii) and the matter after clause (iii)
5	and inserting the following:
6	"(ii) the court may not review the contents and
7	adequacy of any statement of basis and purpose re-
8	quired by section 553(c) of title 5, United States
9	Code, to be incorporated in the rule or order, except $% \left(-1\right) =-1$
10	as part of the record, taken as a whole."; and
11	(iii) by striking subparagraph (C);
12	and
13	(B) in paragraph (2), by striking "any
14	rule" and inserting "any rule or order".
15	(n) Section 20.—Section 20(a)(1) of the Toxic Sub-
16	stances Control Act (15 U.S.C. 2619(a)(1)) is amended
17	by striking "order issued under section 5 " and inserting
18	"order issued under section 4 or 5". ϕ does this need to
19	pull in 6(i) orders?; NO 6(i)
20	(o) Section 21.—Section 21 of the Toxic Substances
21	Control Act (15 U.S.C. 2620) is amended—
22	(1) in subsection (a), by striking "order under
23	section 5(e) or (6)(b)(2)" and inserting "order
24	under section 4 or 5(e) or (f)"; and ødoes this need
25	to pull in 6(i) orders?¿ NO 6(1)

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1	(2) in subsection (b)(1), by striking "order
2	under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and
3	inserting "order under section $4\mathrm{or}5(\mathrm{e})\mathrm{or}(\mathrm{f})$ "; and
4	ϕ does this need to pull in 6(i) orders? ϵ . NO 6(i)
5	(p) Section 24.—Section 24(b)(2)(B) of the Toxic
6	Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is
7	amended—
8	(1) by inserting "and" at the end of clause (i);
9	(2) by striking clause (ii); and
10	(3) by redesignating clause (iii) as clause (ii).
11	(q) Section 26.—Section 26 of the Toxic Substances
12	Control Act (15 U.S.C. 2625) is amended—
13	(1) in subsection (e), by striking "Health, Edu-
14	cation, and Welfare" each place it appears and in-
15	serting "Health and Human Services"; and
16	(2) in subsection (g)(1), by striking "data" and
17	inserting "information".
18	(r) Section 27.—Section 27(a) of the Toxic Sub-
19	$stancesControlAct(15U.S.C.2626(a))isamended-\!$
	[SUSTAINABLE CHEM UNDER DISCUSSION]
20	(1) by striking "Health, Education, and Wel-
21	fare" and inserting "Health and Human Services";
22	(2) by striking "test data" both places it ap-
23	pears and inserting "information";
24	(3) by striking "rules promulgated" and insert-
25	ing "rules, orders, or consent agreements"; and

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1	(4) by striking "standards" and inserting "pro-
2	tocols and methodologies".
3	(s) Section 30.—Section 30(2) of the Toxic Sub-
4	stances Control Act (15 U.S.C. 2629(2)) is amended by
5	striking "rule" and inserting "rule, order, or consent
6	agreement".
7	SEC. 21. NO RETROACTIVITY.
8	Nothing in sections 1 through \$20\;, or the amend-
9	ments made by sections 1 through $\phi 20\xi$, shall be inter-
10	preted to apply retroactively to any State, Federal, or
11	maritime legal action filed before the date of enactment
12	of this Act.
13	SEC. 22. TREVOR'S LAW.
14	(a) Purposes.—The purposes of this section are—
15	(1) to provide the appropriate Federal agencies
16	with the authority to help conduct investigations into
17	potential cancer clusters;
18	(2) to ensure that Federal agencies have the
19	authority to undertake actions to help address can-
20	cer clusters and factors that may contribute to the
21	creation of potential cancer clusters; and
22	(3) to enable Federal agencies to coordinate
23	with other Federal, State, and local agencies, insti-
24	tutes of higher education, and the public in inves-
25	tigating and addressing cancer clusters.

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1	(b) Designation and Investigation of Poten-			
2	TIAL CANCER CLUSTERS.—Part P of title III of the Pub-			
3	lic Health Service Act (42 U.S.C. 280g et seq.) is amended			
4	by adding at the end the following:			
5	"SEC. 399V-6. DESIGNATION AND INVESTIGATION OF PO-			
6	TENTIAL CANCER CLUSTERS.			
7	"(a) Definitions.—In this section:			
8	"(1) CANCER CLUSTER.—The term 'cancer			
9	cluster' means the incidence of a particular cancer			
10	within a population group, a geographical area, and			
11	a period of time that is greater than expected for			
12	such group, area, and period.			
13	"(2) Particular cancer.—The term 'par-			
14	ticular cancer' means one specific type of cancer or			
15	a type of cancers scientifically proven to have the			
16	same cause.			
17	"(3) POPULATION GROUP.—The term 'popu			
18	lation group' means a group, for purposes of calcu-			
19	lating cancer rates, defined by factors such as race,			
20	ethnicity, age, or gender.			
21	"(b) Criteria for Designation of Potential			
22	CANCER CLUSTERS.—			
23	"(1) DEVELOPMENT OF CRITERIA.—The Sec-			
24	retary shall develop criteria for the designation of			
25	potential cancer clusters.			

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1	"(2) REQUIREMENTS.—The criteria developed
2	under paragraph (1) shall consider, as appropriate—
3	"(A) a standard for cancer cluster identi-
4	fication and reporting protocols used to deter-
5	mine when cancer incidence is greater than
6	would be typically observed;
7	"(B) scientific screening standards that
8	ensure that a cluster of a particular cancer in-
9	volves the same type of cancer, or types of can-
10	cers;
11	"(C) the population in which the cluster of
12	a particular cancer occurs by factors such as
13	race, ethnicity, age, and gender, for purposes of
14	calculating cancer rates;
15	"(D) the boundaries of a geographic area
16	in which a cluster of a particular cancer occurs
17	so as not to create or obscure a potential clus-
18	ter by selection of a specific area; and
19	"(E) the time period over which the num-
20	ber of cases of a particular cancer, or the cal-
21	culation of an expected number of cases, occurs.
22	"(c) Guidelines for Investigation of Poten-
23	${\tt TIAL\ CANCER\ CLUSTERS.} {\bfThe\ Secretary,\ in\ consultation}$
24	with the Council of State and Territorial Epidemiologists
25	and representatives of State and local health departments,

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[Discussion Draft]

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1	shall develop, publish, and periodically update guidelines
2	for investigating potential cancer clusters. The guidelines $% \left(x\right) =\left(x\right) +\left(x\right)$
3	shall—
4	"(1) recommend that investigations of cancer
5	clusters—
6	"(A) use the criteria developed under sub-
7	section (b);
8	"(B) use the best available science; and
9	"(C) rely on a weight of the scientific evi-
10	dence;
11	"(2) provide standardized methods of reviewing
12	and categorizing data, including from health surveil-
13	lance systems and reports of potential cancer clus-
14	ters; and
15	"(3) provide guidance for using appropriate epi-
16	demiological and other approaches for investigations.
17	"(d) Investigation of Cancer Clusters.—
18	"(1) Secretary discretion.—The Sec
19	retary—
20	"(A) in consultation with representatives of
21	the relevant State and local health departments,
22	shall consider whether it is appropriate to con-
23	duct an investigation of a potential cancer clus-
24	ter; and

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1	"(B) in conducting investigations shall
2	have the discretion to prioritize certain poten-
3	tial cancer clusters, based on the availability of
4	resources.
5	"(2) COORDINATION.—In investigating poten
6	$tial\ cancer\ clusters,\ the\ Secretary\ shall\ coordinate$
7	with agencies within the Department of Health and
8	Human Services and other Federal agencies, such as
9	$the\ Environmental\ Protection\ Agency.$
10	"(3) BIOMONITORING.—In investigating poten
11	tial cancer clusters, the Secretary shall rely on all
12	appropriate biomonitoring information collected
13	under other Federal programs, such as the National
14	Health and Nutrition Examination Survey. The Sec-
15	retary may provide technical assistance for relevant
16	biomonitoring studies of other Federal agencies.
17	"(e) DUTIES.—The Secretary shall—
18	"(1) ensure that appropriate staff of agencies
19	within the Department of Health and Human Serv
20	ices are prepared to provide timely assistance, to the
21	extent practicable, upon receiving a request to inves-
22	tigate a potential cancer cluster from a State or
23	local health authority;
24	"(2) maintain staff expertise in epidemiology,
25	toxicology, data analysis, environmental health and

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1	cancer surveillance, exposure assessment, pediatric
2	health, pollution control, community outreach, health
3	education, laboratory sampling and analysis, spatial
4	mapping, and informatics;
5	"(3) consult with community members as inves-
6	tigations into potential cancer clusters are con-
7	ducted, as the Secretary determines appropriate;
8	"(4) collect, store, and disseminate reports on
9	investigations of potential cancer clusters, the pos-
10	sible causes of such clusters, and the actions taken
11	to address such clusters; and
12	"(5) provide technical assistance for inves
13	$tigating cancer clusters to State and local health de\cdot$
14	partments through existing programs, such as the
15	Epi-Aids program of the Centers for Disease Control
16	and Prevention and the Assessments of Chemical
17	Exposures Program of the Agency for Toxic Sub-
18	stances and Disease Registry.".

 $F:\label{thm:tscaloud} F:\label{thm:tscaloud} F:\label{thm:tscaloud} This \ language \ is \ provided \ by \ EPA \ as \ technical \ assistance \ in \ response \ to \ a \ congressional \ request. \ The \ technical \ assistance \ in \ response \ to \ a \ congressional \ request.$ assistance is intended for use only by the requester. The technical assistance does not necessarily represent the $policy\ positions\ of\ the\ agency\ and\ the\ administration\ on\ the\ bill,\ the\ draft\ language\ and\ the\ comments.$

[DISCUSSION DRAFT]

1	SEC. \parallel . MANUFACTURING AND PROCESSING NOTICES.
2	Section 5 of the Toxic Substances Control Act (15
3	U.S.C. 2604) is amended—
4	(1) in subsection (a)—
5	(A) in paragraph (1)—
6	(i) by striking "Except as provided
7	in" and inserting "(A) Except as provided
8	in subparagraph (B) of this paragraph
9	and";
10	(ii) by redesignating subparagraphs
11	(A) and (B) as clauses (i) and (ii), respec-
12	tively;
13	(iii) by striking all that follows "sig-
14	nificant new use" and inserting a period;
15	and
16	(iv) by adding at the end the fol-
17	lowing:
18	"(B) A person may take the actions described
19	in subparagraph (A) if—
20	"(i) such person submits to the Adminis-
21	trator, at least 90 days before such manufac-
22	ture or processing, a notice, in accordance with

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(627910|7)

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1	subsection (d), of such person's intention to	
2	manufacture or process such substance and	
3	such person complies with any applicable re-	
4	quirement of or imposed under subsection (b),	
5	(e), or (f); and	
6	"(ii) the Administrator conducts a review	
7	of the notice and either—	
8	"(I) makes a determination under	
9	paragraph (3)(A) and, as necessary, issues	
10	an order under subsection (f)(1); or	
11	"(II) makes a determination under	
12	paragraph (3)(B) and issues an order	
13	under subsection (e)(1)(B)."; and	
14	(B) by adding at the end the following new	
15	paragraphs:	
16	"(3) Review and determination.—Not later	
17	than 90 days after receipt of a notice under para-	
18	graph (1), subject to section 18, Before the end of the applicable review period, subject to section 18, the Administrator shall review such notice and	
	the Administrator shall review such notice and—	Commented [A1]: Redundant text
19	"(A) determine whether the relevant chem-	
20	ical substance or significant new use may	
21	present an unreasonable risk of injury to health	
22	or the environment, without consideration of	
23	costs or other nonrisk factors, including an un-	
24	reasonable risk to a potentially exposed or sus-	
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1	ceptible subpopulation identified as relevant by
2	the Administrator under the conditions of use,
3	and take applicable action under subsection (f)
4	or (g); or
5	"(B) determine that additional information
6	is necessary to make the determination under
7	subparagraph (A), and take applicable action
8	under subsection (e).
9	"(4) Failure to render determination.—
10	"(A) Failure to render determina-
11	TION.—If the Administrator fails to make a de-
12	termination on a notice under paragraph (3) by
13	the end of the applicable review period and the
14	notice has not been withdrawn by the sub-
15	mitter, the Administrator shall refund to the
16	submitter all applicable fees charged to the sub-
17	mitter for review of the notice pursuant to sec-
18	tion 26(b)(1), and the Administrator shall not
19	be relieved of any requirement to make such de-
20	termination.
21	"(B) LIMITATIONS.—(i) A refund of appli-
22	cable fees under subparagraph (A) shall not be
23	made if the Administrator certifies that the
24	submitter has not provided information required
25	under subsections (b) or (e) or has otherwise

1	unduly delayed the process such that the Ad-
2	ministrator is unable to render a determination
3	within the applicable period of review.
4	"(ii) A failure of the Administrator to
5	render a decision shall not be deemed to con-
6	stitute a withdrawal of the notice.
7	"(iii) Nothing in this paragraph shall be
8	construed as relieving the Administrator or the
9	submitter of the notice from any requirement of
10	this section.
11	"(5) ARTICLE CONSIDERATION.—The Adminis-
12	trator may require notification under this section for
13	the import or processing of a chemical substance as
14	part of an article or category of articles under para-
15	graph (1)(B) if the Administrator makes an affirma-
16	tive finding in a rule under paragraph (2) that the
17	reasonable potential for exposure to the chemical
18	substance through the article or category of articles
19	subject to the rule justifies notification.";
20	(2) in subsection (b)—
21	(A) in the subsection heading, by striking
22	"Test Data" and inserting "Information";
23	(B) in paragraph (1)—
24	(i) in subparagraph (A)—

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1	(I) by striking "test data" and
2	inserting "information"; and
3	(II) by striking "such data" and
4	inserting "such information"; and
5	(ii) in subparagraph (B), by striking
6	"test data" and inserting "information";
7	(C) in paragraph (2)—
8	(i) in subparagraph (A)—
9	(I) by striking "test data" and
10	inserting "information";
11	(II) by striking "shall" and in-
12	serting "may"; and
13	(III) by striking "data pre-
14	scribed" and inserting "information
15	prescribed"; and
16	(ii) in subparagraph (B)—
17	(I) by striking "Data" and in-
18	serting "Information";
19	(II) by striking "data" both
20	places it appears and inserting "infor-
21	mation"; and
22	(III) by striking "show" and in-
23	serting "shows";
24	(D) in paragraph (3)—

1	(i) by striking "Data" and inserting
2	"Information"; and
3	(ii) by striking "paragraph (1) or (2)"
4	and inserting "paragraph (1) or (2) of this
5	subsection or under subsection (e)"; and
6	(E) in paragraph (4)—
7	(i) in subparagraph (A)(i), by insert-
8	ing ", without consideration of costs or
9	other nonrisk factors" after "health or the
10	environment"; and
11	(ii) in subparagraph (C), by striking
12	", except that" and all that follows
13	through "subparagraph (A)";
14	(3) in subsection (c)—
15	(A) in the subsection heading, by inserting
16	"AND REVIEW" after "Notice"; and
17	(B) by striking "before which" and all that
18	follows through "subsection may begin";
19	(4) in subsection (d)—
20	(A) by striking "test data" in paragraph
21	(1)(B) and inserting "information";
22	(B) by striking "data" each place it ap-
23	pears in paragraph (1)(C) and paragraph (2)
24	and inserting "information":

7

1	(C) in paragraph (2)(B), by striking "uses
2	or intended uses of such substance" and insert-
3	ing "uses of such substance identified in the no-
4	tice and any additional uses of such substance
5	that are reasonably foreseeable by the Adminis-
6	trator"; and
7	(D) in paragraph (3)—
8	(i) by striking "for which the notifica-
9	tion period prescribed in subsection (a),
10	(b), or (c)" and inserting "for which the
11	applicable review period"; and
12	(ii) by striking "such notification pe-
13	riod" and inserting "such period";
14	(5) by amending subsection (e) to read as fol-
15	lows:
16	"(e) Regulation When Available Information
17	Is Insufficient.—(1) If the Administrator determines
18	that the information available to the Administrator is in-
19	sufficient to permit the Administrator to make a deter-
20	mination in accordance with subsection (a)(3)(A) for a
21	chemical substance or significant new use with respect to constant and respect to constant respect t
22	which notice is required by subsection (a)—
23	"(A) the Administrator—

1	"(i) shall provide an opportunity for the
2	submitter of the notice to submit the additional
3	information within the applicable review period;
4	"(ii) may, by agreement with the sub-
5	mitter, extend the applicable review period for
6	a reasonable time to allow the development and
7	submission of the additional information including under
8	section 4; and
9	"(iii) on receipt of the additional informa-
10	tion complying with a rule, testing consent
11	agreement, or order issued under section 4,
12	may extend the review period not more than 90
13	days to make a decision; not later than 90 days after receipt of sufficient information under clause (i) or information complying with a rule, consent agreement, or order under section 4, shall make the determination under subsection (a)(3)(A)" and
14	"(B) the Administrator may issue an order to
15	take effect on the expiration of the applicable review
16	period to prohibit or otherwise restrict the manufac-
17	ture, processing, distribution in commerce, use, or
18	disposal of the chemical substance, or manufacture
19	or processing of the chemical substance for a signifi-
20	cant new use, or any combination of such activities,
21	sufficient to allay the Administrator's initial concern
22	that, in the absence of sufficient information, the
23	substance or significant new use may present an un-
24	reasonable risk of injury to health or the environ-

Commented [A2]: Shouldn't this just say "under clause (i) or (ii)??

Commented [A3]: This changed text seems problematic because it does not provide for extension of the review period and therefore leaves open the question of whether the determination described in (iii) occurs after the review period.

Both of these issues could be addressed by rewording the new text as follows: "not later than 90 days after receipt of sufficient information under clause (i) or (ii), which shall extend the review period by 90 days, shall make the determination under subsection (a)(3)(A)."

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25 ment.

- 1 "(2) In selecting among prohibitions and other re-
- 2 strictions to include in an order to be issued by the Admin-
- 3 istrator to meet the standard under paragraph (1), the
- 4 Administrator shall consider, to the extent practicable
- 5 based on reasonably available information, costs and other
- 6 nonrisk factors.
- 7 "(3) If the Administrator issues an order under para-
- 8 graph (1), the submitter of the notice under subsection
- 9 (a) may commence manufacture of the chemical sub-
- 10 stance, or manufacture or processing of the chemical sub-
- 11 stance for a significant new use, pursuant to this sub-
- 12 section only in compliance with the restrictions specified
- 13 in the order.
- "(4) Not later than 90 days after issuing an order
- 15 under paragraph (1), the Administrator shall consider
- 16 whether to promulgate a rule pursuant to subsection
- 17 (a)(2) that identifies as a significant new use any manu-
- 18 facturing, processing, use, distribution in commerce, or
- 19 disposal of the chemical substance that does not conform
- 20 to the restrictions imposed by the order, and, as applica-
- 21 ble, initiate such a rulemaking or publish a statement de-
- 22 scribing the reasons of the Administrator for not initiating
- 23 such a rulemaking.
- "(5) An order may not be issued under paragraph
- 25 (1) respecting a chemical substance—

1	"(A) later than 45 days before the expiration of
2	the notification period applicable to the manufacture
3	or processing of such substance under subsection
4	(a), (b), or (c); and
5	"(B) unless the Administrator has, on or before
6	the issuance of the order, notified, in writing, each
7	manufacturer or processor, as the case may be, of
8	such substance of the determination which underlies
9	such order.";
10	(6) by amending subsection (f) to read as fol-
11	lows:
12	"(f) Protection Against Potential Unreason-
13	ABLE RISKS.—
14	"(1) Orders.—If the Administrator determines
15	that the manufacture, processing, distribution in
16	commerce, use, or disposal of a chemical substance
17	or a significant new use with respect to which notice
18	is required by subsection (a), or that any combina-
19	tion of such activities, may present an unreasonable
20	risk of injury to health or the environment in ac-
21	cordance with subsection $(a)(3)(A)$ —
22	"(A) the Administrator shall issue an
23	order, to take effect on or before the expiration
24	of the applicable review period to prohibit or
25	otherwise restrict the manufacture, processing,

distribution in commerce, use, or disposal of the
chemical substance, or of the chemical sub-
stance for a significant new use, sufficient to
allay the Administrator's initial concern that
the substance or significant new use may
present an unreasonable risk of injury to health
or the environment;
"(B) no person may commence manufac-
ture of the chemical substance, or manufacture
or processing of the chemical substance for a
significant new use, pursuant to this subsection
except in compliance with the restrictions speci-
fied in the order; and
"(C) not later than 90 days after issuing
an order under subparagraph (A), the Adminis-
trator shall consider whether to promulgate a
rule pursuant to subsection (a)(2) that identi-
fies as a significant new use any manufac-
turing, processing, use, distribution in com-
merce, or disposal of the chemical substance
that does not conform to the restrictions im-
posed by the order, and, as applicable, initiate

such a rulemaking or publish a statement de-

scribing the reasons of the Administrator for

not initiating such a rulemaking.

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1	"(2) SELECTING PROHIBITIONS AND RESTRIC-
2	TIONS.—In selecting among prohibitions and other
3	restrictions to include in an order to be issued by
4	the Administrator to meet the standard under para-
5	graph (1), the Administrator shall consider, to the
6	extent practicable based on reasonably available in-
7	formation, costs and other nonrisk factors, and such
8	an order shall include a may include any requirement described in
9	section 6(a).
10	"(3) Persistent and bioaccumulative sub-
11	STANCES.—For a chemical substance that is subject
12	to the requirements of this subsection and that the
13	Administrator determines, with respect to persist-
14	ence and bioaccumulation, scores high for 1 and ei-
15	ther high or moderate for the other, pursuant to the
16	TSCA Work Plan Chemicals Methods Document
17	published by the Administrator in February 2012
18	(or a successor scoring system), the Administrator
19	shall, in selecting among prohibitions and other re-
20	strictions to include in an order to be issued by the
21	Administrator to meet the standard under para-
22	graph (1), reduce the potential for exposure to the
23	substance to the extent practicable.
24	"(4) Workplace exposures.—To the extent
25	practicable, the Administrator shall consult with the

	13
1	Assistant Secretary of Labor for Occupational Safe-
2	ty and Health prior to adopting any prohibition or
3	other restriction under this subsection to address
4	workplace exposures.";
5	(7) by amending subsection (g) to read as fol-
6	lows:
7	"(g) Statement on Administrator Finding.—If
8	the Administrator finds, in accordance with subsection $% \left(1\right) =\left(1\right) \left(1\right$
9	(a)(3)(A), that a determination that the relevant chemical
10	substance or significant new use may present an unreason-
11	$able\ risk\ of\ injury\ to\ health\ or\ the\ environment\ is\ notwarder above the environment is\ no$
12	ranted, then notwithstanding any remaining portion of the
13	applicable review period, the submitter of the notice may $% \left(1\right) =\left(1\right) \left(1\right) \left($
14	commence manufacture $\overline{\text{for commercial purposes}}$ of the
15	chemical substance or manufacture or processing $\overline{\text{for a}}$
16	${\color{red} \textbf{commercial purpose}} for a significant new use, and the Ad-$
17	ministrator shall make public a statement of the Adminis-
18	trator's finding. Such a statement shall be submitted for
19	publication in the Federal Register as soon as is prac-
20	ticable before the expiration of such period. Publication
21	of such statement in accordance with the preceding sen-
22	tence is not a prerequisite to the manufacturing or proc-
23	essing of the substance with respect to which the state-
24	ment is to be published.";
25	(8) in subsection (h)—

1	(A) in paragraph (1)(A), by inserting ",
2	including an unreasonable risk to a potentially
3	exposed or susceptible subpopulation identified
4	by the Administrator for the specific uses iden-
5	tified in the application" after "health or the
6	environment";
7	(B) in paragraph (1)(B), by striking "appropriate" and inserting "warranted"
8	(B) in paragraph (2), by striking "data"
9	each place it appears and inserting "informa-
10	tion"; and
11	(C) in paragraph (4), by striking ". A rule
12	promulgated" and all that follows through "sec-
13	tion 6(c)" and inserting ", including an unrea-
14	sonable risk to a potentially exposed or suscep-
15	tible subpopulation identified by the Adminis-
16	trator under the conditions of use"; and
17	(9) by amending subsection (i) to read as fol-
18	lows:
19	"(i) Definitions.—(1) For purposes of this section,
20	the terms 'manufacture' and 'process' mean manufac-
21	turing or processing for commercial purposes.
22	"(2) For purposes of this Act, the term 'requirement'
23	as used in this section shall not displace any statutory or
24	common law.
25	$\hbox{``(3) For purposes of this section, the term `applicable'}\\$

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 $\,\,26\,\,$ review period' means the period starting on the date the

- 1 Administrator receives a notice under subsection (a)(1)
- 2 and ending on the date the Administrator makes a deter-
- 3 mination under subsection (a)(3)(A), as extended pursu-
- 4 ant to subsection (c) or (e)(1)(A). and ending on the date that is 90 days thereafter, as extended pursuant to subsection (b), (c) or (e).".

Commented [A4]: Per comment above, (e)(1)(A)(i) and (ii) provide for extension, but e1Aiii, which gives EPA 90 days after receipt of information to render a determination, does not expressly create and extension of the review period.

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/19/2016 8:38:52 PM

To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]

Subject: Sen. Udall TSCA TA request on Sec. 5

Jonathan – will do. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]

Sent: Tuesday, April 19, 2016 4:38 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: EPA TA request on Sec. 5

A short call would also be helpful. Let us know when they can do so. thanks.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, April 19, 2016 4:37 PM

To: Black, Jonathan (Tom Udall) < Jonathan Black@tomudall.senate.gov>

Subject: RE: EPA TA request on Sec. 5

Jonathan – yes, thanks for flagging. We agree and are developing some additional revised TA to send shortly. I'll share this with folks to make sure we're looking at the right version. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]

Sent: Tuesday, April 19, 2016 4:35 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: EPA TA request on Sec. 5

Hi Sven, it isn't clear to us that your team reviewed the right Sec. 5 document that we received from HLC. I'm reattaching that section 5 along with comments we put on your TA.

We really want your take on the changes made to subsection (e)(1)(A) in the case of EPA requiring testing. The latest draft says the review period in such case can only be extended by agreement with the submitter, which makes no sense to us. Folks also point to subsection (c)'s "good cause" language, but extensions there are limited to a maximum of 90 days which may not always be enough.

We think this is the only unresolved issue. Can we also get on the phone with you as soon as your team is available for a quick question on Sec. 5?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 3/16/2016 10:56:58 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

Subject: Re: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Got it- checking

On Mar 16, 2016, at 6:37 PM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

Does this work for 14(c)(3)

(1) <!--[if !supportLists]--><!--[endif]-->BAN OR PHASE-OUT.—(A) If the Administrator promulgates a rule pursuant to section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any information under this section with respect to the chemical substance shall no longer apply, subject to subsections (g)(1) (g)(2) and (g)(3).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, March 15, 2016 4:43 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Michal – please see the requested followup TA on CBI and health and safety studies.

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

Response: EPA would interpret the highlighted language to effect no changes in either EPA practice or the Senate passed bill. EPA has always addressed the mix of CBI and non-CBI information in a particular document, assessing what needs to be protected and what does not, which is what the second highlighted text appears to require.

That said, others may argue that the *new* highlighted text does effectuate a change in both the bill and practice. EPA would not interpret (c)(2) as a condition or limitation on (c)(1), because it merely provides that information that is protectable remains protectable even if mixed with non-protectable information, a position EPA already takes. However, the new highlighted text might be argued to indicate that (c)(2) in some way limits or conditions the scope of information releasable pursuant to (c)(1).

Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Tuesday, March 15, 2016 1:16 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: Sen. Markey TSCA TA Request on CBI - health and safety studies

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

- (c) Information Not Protected From Disclosure.—
- (1) IN GENERAL.—Notwithstanding subsections (a) and (b), and subject to paragraph (2), the following information shall not be protected from disclosure:
 - (A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—
 - (i) IN GENERAL.—Subject to clause (ii)—
 - (I) any health and safety study that is submitted under this Act with respect to—
 - (aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or
 - (bb) any chemical substance or mixture for which-
 - (AA) testing is required under section 4; or
 - (BB) a notification is required under section 5; or
 - (II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).
 - (ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—
 - (I) a process used in the manufacturing or processing of a chemical substance or mixture; or
 - (II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.
 - (B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:
 - (i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).
 - (ii) A safety assessment developed, or a safety determination made, under section 6.
 - (iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.
 - (iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.
- (2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, March 15, 2016 1:13 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA Request on CBI - health and safety studies

Michal,

This responds to your TA request on CBI and health and safety studies.

Question: Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

EPA Response: The companies provide a sanitized version of the submission which is what we publish, assuming no final determination has been made regarding eligibility for confidential treatment.

Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Tuesday, March 15, 2016 10:32 AM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: TA - health and safety studies

Sven

Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

Thx

Μ

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 3/23/2016 2:02:20 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

Subject: Re: Sen. Markey TSCA TA - another 6(a) alternative

Michal- It was not in response to that one. It was in response to the email at 9:56 am yesterday with three similar variants. Please let me know if any additional questions. Thanks,

Sven

On Mar 23, 2016, at 9:13 AM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov> wrote:

Just making sure that the note walternatives that you sent last night was not in response to this one. Basically just want confirmation that the 2 alternatives I have pasted below both work for you and don't insert costs into anything?

(a) <!--[if !vml]--><image001.png><!--[endif]--> <!--[if !vml]--><image002.png><!--[endif]--> <!--[if !vml]--><image003.png><!--[endif]--> <!--[if !vml]--><image003.png><!--[endif]--> <!--[if !vml]--><image003.png><!--[endif]--> <!--[if !vml]--><image005.png><!--[endif]--> <!--[if !vml]--><

SCOPE OF REGULATION—If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, then the Administrator shall by rule, and subject to section 18, apply one or more of the following requirements to such substance or mixture to the extent necessary [to ensure/so] that the chemical substance does not present such unreasonable risk, as determined in accordance with subsection (b)(4)(A), under the intended conditions of use. In selecting the particular requirement or requirements to be applied pursuant to this subsection, the Administrator shall, in accordance with subsection (c)(2), take into consideration costs and other factors in choosing among the requirements evaluated.

Director of Oversight & Investigations Office of Senator Edward J. Markey 255 Dirksen Senate Office Building Washington, DC 20510 202-224-2742

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<image006.png><image007.png><image012.png><image013.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, March 22, 2016 3:19 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA - another 6(a) alternative

Michal,

This TA responds to the request to review a 6(a) option dealing with section 18 and (c)(2) references.

OPTION 2

(a) <!--[if !vml]--><image001.png><!--[endif]--> <!--[if !vml]--><image002.png><!--[endif]--> <!--[if !vml]--><image003.png><!--[endif]--> <!--[if !vml]--><image003.png><!--[endif]--> <!--[if !vml]--><image005.png><!--[endif]--> <!--[if !vml]--><

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

The changes you suggest do help address the specific issue we identified in our most recent TA -- the suggestion that section 18 and 6(c)(2) are on the same footing as limitations on EPA's authority. However, it does not address our long standing point that we think the reference to section 18 in this context is unnecessary and confusing. We understand your point about addressing Geier, but we think section 18 already does that (and if it doesn't, it's hard to see how a reference to it in section 6 would). The reference to section 18 in section 6(c) of the offer indicates that EPA's *authority* to promulgate rules under section 6(c) is limited in some way by section 18, which we do not understand to be your intent. Presumably, you mean to say that the *preemptive effect* of any rules EPA promulgates under section 6(c) is subject to section 18. (And, again, we don't really see the value of making such a point in section 6, since section 18 already provides that it governs the preemptive effect of section 6 rules, and has whatever effect it has with respect to Geier.)

Please let me know if any questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Monday, March 21, 2016 12:17 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov >

Subject: another 6(a) alternative

OPTION 2

(a) <!--[if !vml]--><image001.png><!--[endif]--> <!--[if !vml]--><image002.png><!--[endif]--> <!--[if !vml]--><image003.png><!--[endif]--> <!--[if !vml]--><image003.png><!--[endif]--> <!--[if !vml]--><image004.png><!--[endif]--> <!--[if !vml]--><image005.png><!--[endif]--> <!--[if !vml]--><

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey <image006.png><image012.png><image013.jpg>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 2/17/2016 4:14:22 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

Subject: Sen. Markey TSCA TA request - Section 4, parties to testing

Michal,

This TA responds to your followup request. Please leg me know if any additional questions. Thanks, Sven

Simply striking "order, or consent agreement" from 4(b)(2)(A) wouldn't restore sense to the paragraph. Respecting rules issued under subsection (a), there would still remain a problem with 4(b)(2)(B) directing the reader to non-existent finding provisions ((a)(1)(A)(ii)) and (a)(1)(B)(ii)).

More broadly, paragraph (4)(b)(2) is structured as a constraint on EPA's discretion to identify the scope of persons who would be subject to testing requirements for a particular rule, order, or consent agreement. Since the paragraph is a constraint on authority, it is not necessary in order for EPA to exercise its underlying testing authorities. Striking the paragraph would give EPA broad authority to require entities to conduct testing – including entities that are not manufacturers or processors of the chemical. Whether you should strike or update the paragraph depends on your the policy objectives.

On Feb 12, 2016, at 5:32 PM, "Freedhoff, Michal (Markey)" < Michal Freedhoff@markey.senate.gov> wrote:

Sven

This is in reference to the EPA TA that pointed out that Section 4(b)(2) in what I sent you doesn't work with Senate 4(a).

Would it make sense to strike "order or CA" and then leave the provision related to rule authority? Is it necessary to specify who EPA can direct to test things at all (ie should we strike the whole thing)?

- (2)(A) A rule, order, or consent agreement under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.
- (B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule, order, or consent agreement under subsection (a):
 - (i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the manufacture of such substance or mixture.
 - (ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding de-scribed in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the processing of such substance or mixture.
 - (iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

Michal Ilana Freedhoff, Ph.D.
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202-224-2742

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/23/2016 10:14:40 PM

To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]

CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall)

[Jonathan Black@tomudall.senate.gov]

Subject: Re: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal - got it - checking. Thanks, Sven

On Apr 23, 2016, at 6:13 PM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

Ty – any issues w these edits?

<!--[if !supportLists]--><!--[endif]-->Page 150 line 19 – Insert "the date on which" before "an order"

<!--[if !supportLists]--><!--[endif]-->Page 150 line 19 – Insert "is issued" after "an order"

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Saturday, April 23, 2016 6:12 PM

To: Freedhoff, Michal (Markey)

Cc: Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall) **Subject:** Re: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal,

Revised TA on section 19 with house changes annotated.

Section 19 – Sec. 19.XML comments

Page 1 – remove all brackets DONE

Page 1 line 6 to 19 -- consolidate this material in paragraph (a)(1), perhaps as a new (a)(1)(C). Per EPA TA to ensure that low priority decisions are covered by the judicial review provisions of subsection (c). DONE

Page 2 line 9 – remove brackets from "Except as otherwise provided by this title" DONE

Page 2 line 13 – remove brackets from "6(i)(1)" DONE

Page 2 lines 18 to 25 – remove all brackets DONE

Page 3 line 6 – remove brackets from "6(i)(1)" DONE

Page 4, line 2– strike lines 2 through 21, and insert:

"by amending subsection (c)(1)(B)(i) to read: "(i) in the case of review of a rule under section 4(a), 5(b)(4), 6(a) (including review of the associated determination under section 6(b)(4)(A)) or 6(e), or an order under 6(i)(1) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule or order if the court finds that the rule or order is not supported by substantial evidence in the record including any matter in the record taken as a whole;" DONE EXCEPT SUBSTANTIAL EVIDENCE DIRECTION FOR RULES AND ORDERS IS DIVIDED INTO SEPARATE SUBCLAUSES AND REVIEW OF TEST ORDERS UNDER SECTION 4 IS ADDED TO SUBSTANTIAL EVIDENCE REVIEW.

Page 5 line 7-8 – Strike the brackets before (iii) DONE

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

On Apr 23, 2016, at 4:30 PM, Freedhoff, Michal (Markey) < Michal Freedhoff@markey.senate.gov > wrote:

Just verifying before proceeding that you checked conforming edits at the end of the bill?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Saturday, April 23, 2016 4:29 PM

To: Freedhoff, Michal (Markey); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)

Subject: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal,

While we continue to work on the TA requests on 14 and other sections, we wanted to pass along TA on house section 19 (4-23).

The House discussion draft leaves section 19 from current TSCA un-amended, except for the addition of judicial review of low-priority determinations. Thus, in contrast to the Senate bill and offer, it does not:

- -- provide for judicial review of test orders under section 19
- -- provide for judicial review of rules other than the rules currently enumerated in section 19
- -- provide for judicial review of determinations that a chemical substance does not present unreasonable risk under section 19 (including the substantial evidence review the senate bill and offer would afford).

Note that this does not mean that these EPA actions will not be judicially reviewable. Rather, they would be reviewable in federal district court, rather than the court of appeals, and would be subject to the general federal 6-year review period, rather than the 60 days provided for in section 19.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/5/2016 2:34:42 PM

To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: Sen. Markey TSCA TA on Section 4

Michal,

We are working on your last night's section 4 and meeting internally at 11 to go over it. Do you still want our comments on last night's version? Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Tuesday, April 05, 2016 10:29 AM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: Sen. Markey TSCA TA on Section 5 - early morning

Thank you, ai am re-drafting yet another section 4, pls stand by for that in the next hour or so I hope.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey









From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, April 05, 2016 10:26 AM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA on Section 5 - early morning

Michal – TA responding to your comments on section 5 attached. EPA comments in blue. Please let me know

if any questions. Thanks,

Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753 From: Freedhoff, Michal (Markey) [mailto:Michal Freedhoff@markey.senate.gov]

Sent: Tuesday, April 05, 2016 6:00 AM

To: Kaiser, Sven-Erik < Kaiser, Sven-Erik@epa.gov>

Subject: Fw: Section 5

Sven - comments in yellow are for you, changes marked with blank comment boxes and a couple in green for Dimitri. Pls take one more FAST look, need to get this to the House asap.

Michal Ilana Freedhoff, Ph.D. Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]

Sent: 4/13/2016 5:57:54 PM

To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]

Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan, Definitely today – I'll let you know if any questions come up. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]

Sent: Wednesday, April 13, 2016 1:57 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

No. I want them to do a good job. Hopefully COB today? let me know if not possible.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Wednesday, April 13, 2016 1:56 PM

To: Black, Jonathan (Tom Udall) < <u>Jonathan Black@tomudall.senate.gov</u>> **Subject:** RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan, we're working on it – is there a drop dead time I should tell folks. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]

Sent: Wednesday, April 13, 2016 1:52 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov >

Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Checking in...

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Tuesday, April 12, 2016 6:33 PM

To: Black, Jonathan (Tom Udall) < <u>Jonathan Black@tomudall.senate.gov</u>> **Subject:** RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Ok - thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan Black@tomudall.senate.gov]

Sent: Tuesday, April 12, 2016 6:32 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: Re: Sen. Udall TSCA TA request on Industry nominated chemicals

Yes, thanks.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik

Sent: Tuesday, April 12, 2016 6:26 PM **To:** Black, Jonathan (Tom Udall)

Subject: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,

Got it - checking. Tomorrow ok? Thanks,

Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan Black@tomudall.senate.gov]

Sent: Tuesday, April 12, 2016 6:19 PM

To: Kaiser, Sven-Erik < Kaiser.Sven-Erik@epa.gov>

Subject: FW: Sen. Udall TSCA TA request on Industry nominated chemicals

Would appreciate thoughts on these edits/suggestions from EDF

Attached see our additions to EPA's rewrite of section 6(b)(4)(E), which:

- Include consistently missed deadlines for risk evaluations and rules as an additional critical indicator of EPA being overrun by industry requests;
- Preclude EPA from allocating disproportionately more resources to industry-requested chemicals, a concept that is already in the current text; and
- Require EPA, when selecting among industry requests, to give preference to those presenting greater concern
 using the criteria specified in the prioritization section.

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]

Sent: Tuesday, April 12, 2016 2:02 PM

To: Richard Denison; Joanna (joannaslaney@gmail.com)

Subject: FW: Sen. Udall TSCA TA request on Industry nominated chemicals

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]

Sent: Monday, April 11, 2016 5:20 PM

To: Black, Jonathan (Tom Udall) < <u>Jonathan Black@tomudall.senate.gov</u>> **Subject:** Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan.

This TA responds to the request on industry nominated chemicals language.

You requested a replacement for (b)(4)(E) that would eliminate the industry cap, but nonetheless provide comparable assurance that industry prioritizations would not overrun the resources necessary for EPA priorities.

We believe the following replacement for (E)(i) and (ii) would accomplish this objective. It operates by simply shutting down the pipeline for taking further industry requests if EPA falls behind on the expected pace of pursuing its own priorities. The edits are also attached as a redline to section 6 (attached).

(E) LIMITATION AND CRITERIA

- "(i) If the Administrator's designation of priority substances or conduct of risk evaluations is insufficient to satisfy the requirements of paragraph (2)(A), (2)(B), or (2)(C), then the Administrator shall accept no further requests under subparagraph (C)(ii) until the requirements of paragraph (2)(A), (2)(B), and (2)(C) are all satisfied
- (ii) Requests for risk evaluations under subparagraph (C)(ii) shall be subject to public notice and comment and to the payment of fees pursuant to section 26(b)(3)(D), and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations,

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser U.S. EPA Office of Congressional and Intergovernmental Relations 1200 Pennsylvania Ave., NW (1305A) Washington, DC 20460 202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan Black@tomudall.senate.gov]

Sent: Monday, April 11, 2016 1:44 PM

To: Kaiser, Sven-Erik < Kaiser. Sven-Erik@epa.gov>

Subject: Re: Sen. Udall TSCA TA request on Industry nominated chemicals

Thanks Sven, I should have asked for you to draft to the Senate offer.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik

Sent: Monday, April 11, 2016 1:33 PM **To:** Black, Jonathan (Tom Udall)

Subject: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,

This TA responds to the request on industry nominated chemicals.

QUESTION: EPA has indicated that the House bill allows industry nominated chemicals to overwhelm EPA's priorities.

Is there a way to draft the house bill/proposal to allow for industry nominated chemicals to move through "without a cap" (as per the senate bill), but also without compromising EPA's priorities?

Response:

The language in question is for the House offer. It would also work with minor adjustment for the House bill as passed. There is no min/max provision in the House bill as passed, so that part has to be deleted if you are modifying the House bill as passed.

House offer

6(b)(7) MINIMUM NUMBER.--

- (A) IN GENERAL.-- Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.
- (B) LIMITATION.-- Notwithstanding any other provision of this section, if the Administrator does not initiate 10 or more risk evaluations under (A) in any complete fiscal year following the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, then in the following fiscal year the Administrator shall not accept any requests under paragraph (3)(A)(ii) and is not subject to paragraph (3)(C)(i)(I), unless in that fiscal year the Administrator has first initiated 10 risk evaluations under (A).

House bill as passed

6(b)(7) MINIMUM NUMBER.--

- (A) IN GENERAL.-- Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.
- (B) LIMITATION.-- Notwithstanding any other provision of this section, if the Administrator does not initiate 10 or more risk evaluations under (A) in any complete fiscal year following the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, then in the following fiscal year the Administrator shall not accept any requests under paragraph (3)(A)(ii) unless in that fiscal year the Administrator has first initiated 10 risk evaluations under (A).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks, Sven

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> From: "Black, Jonathan (Tom Udall)" < <u>Jonathan Black@tomudall.senate.gov</u>> Date: April 10, 2016 at 6:07:41 PM EDT

To: "Kaiser, Sven-Erik" < <u>Kaiser.Sven-Erik@epa.gov</u>>

Subject: Industry nominated chemicals

Hi Sven,

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